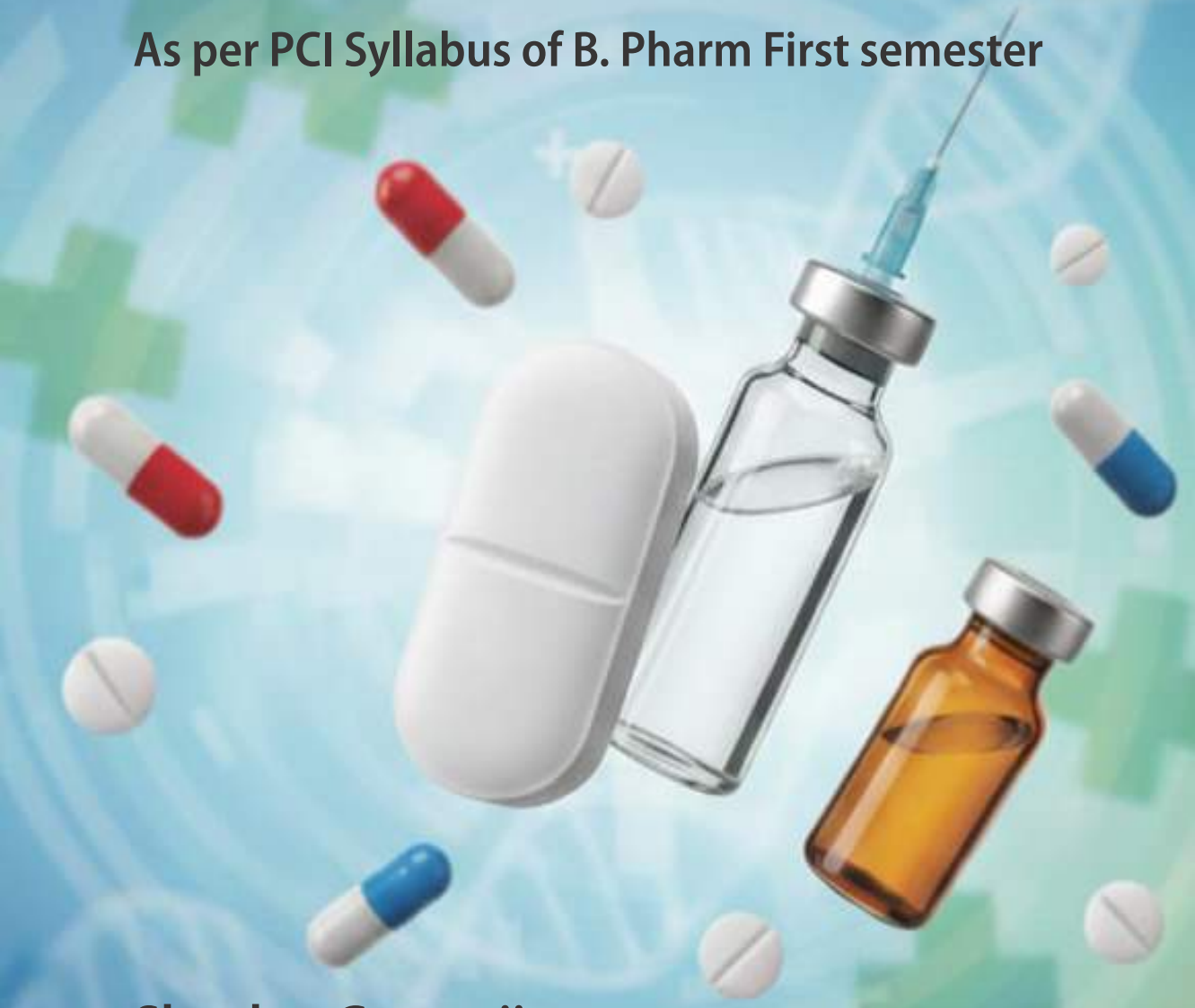
Textbook of Pharmaceutics-I

As per PCI Syllabus of B. Pharm First semester



Shankar Gavaroji

Mantra Publication

DeepScience

Textbook of Pharmaceutics-I

This Book is designed strictly as per the latest PCI syllabus. It provides clear, student-friendly explanations of core pharmaceutics concepts. The book is highly useful for B.Pharm 1st Semester students. It serves as a reliable guide for foundational topics, helping students build strong pharmaceutical knowledge.

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PREFACE

Pharmaceutics forms the backbone of pharmaceutical sciences, linking the basic principles of chemistry and biology to the practical aspects of preparing safe and effective medicines. Understanding this subject at the beginning of a pharmacy career is essential, as it builds the foundation for all advanced courses and future professional responsibilities. With this thought in mind, this book, *Textbook of Pharmaceutics-I*, has been prepared to meet the academic needs of B.Pharm first-year students.

This textbook has been written strictly in accordance with the latest syllabus prescribed by the Pharmacy Council of India (PCI). Every chapter has been organized to present concepts in a simple, systematic, and student-friendly manner. The aim is to help learners grasp the fundamentals of dosage forms, pharmaceutical calculations, unit operations, and various processes involved in the development of medicines. Special care has been taken to maintain clarity, accuracy, and relevance throughout the content.

While writing this book, emphasis has been placed on bridging theoretical knowledge with practical understanding. Illustrations, examples, and explanations are included to support students in connecting classroom learning with real-world pharmaceutical applications. The language has been kept clear and approachable so that even beginners in the subject can learn with confidence.

It is my sincere hope that this book serves as a helpful guide for students as they begin their journey into the world of pharmaceutics. I welcome constructive suggestions from teachers, students, and fellow professionals for the improvement of future editions. Their feedback will undoubtedly contribute to enhancing the quality and usefulness of this work.

- **Shankar Gavaroji**

ACKNOWLEDGEMENT

The completion of this textbook, *Textbook of Pharmaceutics-I*, has been a journey filled with learning, constant exploration, and sincere effort. I take this opportunity to express my deep sense of gratitude to everyone who contributed, directly or indirectly, to the successful preparation of this work.

I am profoundly thankful to the Almighty for granting me the strength, clarity of thought, and perseverance needed throughout the writing and revision process. Without this guidance and inner support, the task of compiling a comprehensive and student-friendly text would not have been possible.

I extend my heartfelt appreciation to the Pharmacy Council of India (PCI) for framing a well-structured and scientifically sound syllabus. The updated curriculum served as a clear roadmap while developing the content and helped ensure that this book meets the academic requirements of B.Pharm first-year students. I am also grateful to the academic bodies and educators who continue to refine pharmacy education in India, thereby motivating authors and teachers to maintain high-quality standards.

My sincere thanks go to the respected teachers, mentors, and colleagues who encouraged me at every stage. Their constructive suggestions, insightful feedback, and continuous motivation helped refine the material and enrich the overall quality of the book. I am especially thankful to those who reviewed specific chapters, verified technical details, and provided their valuable expertise whenever needed.

A special word of appreciation is reserved for my students, whose enthusiasm for learning and inquisitive questions inspired me to present each concept with clarity and simplicity. Their genuine curiosity and eagerness to understand the subject remind me of the true purpose of academic writing. This book is shaped to support their foundational learning, and I hope it serves them well in their professional journey.

I owe heartfelt gratitude to my family for their unconditional support, patience, and understanding throughout the long hours dedicated to writing. Their encouragement, belief, and emotional strength provided me with the motivation to continue working even during challenging phases. Their presence has been a constant source of reassurance.

Lastly, I wish to acknowledge all individuals, institutions, and resources that contributed—directly or indirectly—to the completion of this textbook. Whether through professional guidance, discussions, access to reference materials, or moral support, each contribution has been meaningful and deeply appreciated.

With sincere thanks to all,

- **Shankar Gavaroji**

UNIT - I

HISTORY OF PROFESSION OF PHARMACY IN INDIA IN RELATION TO PHARMACY EDUCATION

The history of pharmacy as a profession in India is closely linked to the evolution of pharmacy education across the country. The roots of formal pharmaceutical learning can be traced back to the mid-19th century, when modern medicine began taking shape under British rule. The earliest structured pharmacy training started in 1860 at Madras Medical College, where students were taught the fundamentals of compounding, dispensing, and labelling medicines. At this stage, the focus was primarily on preparing assistants who could support physicians by compounding formulations, as medicines were not available in ready-made industrial forms.

By the early decades of the 20th century, the demand for trained personnel grew, pushing institutions to introduce more organized curricula. **A** two-year diploma course for "Chemists and Druggists" was launched in 1937 at Madras Medical College and at Visakhapatnam. This course included subjects like Materia Medica, Chemistry, and Practical Pharmacy. Around the same period, a compounder's course was also introduced in Bengal, Bihar, Bombay, and the United Provinces (now Uttar Pradesh). In the Portuguese colony of Goa, an advanced diploma in pharmacy was implemented, marking one of the earliest attempts to create higher-level technical training for pharmacy professionals.

A major milestone in the academic progress of pharmacy was achieved with the launch of the first degree-level program, B.Sc. in Pharmaceutical Chemistry**,** at Banaras Hindu University (BHU) in 1932. This initiative was championed by Prof. Mahadev Lal Schroff, who is often celebrated as the *Father of Modern Indian Pharmacy Education*. Five years later, in 1937, BHU advanced further by initiating a full-fledged three-year Bachelor of Pharmacy (B.Pharm) program, supported by a dedicated team of pharma pioneers including G.P. Srivastava, N.K. Basu, G.B. Singh, S. Prasad, D.N. Majumdar, and N.C. Neogi. These developments created a nationwide momentum, motivating several other universities—such as Andhra University, Madras University, the University of Bombay, Punjab University, and Lallubhai Motilal College of Pharmacy in Ahmedabad—to introduce formal pharmacy programs.

After Independence, pharmacy education continued to expand rapidly. The Department of Pharmacy at Birla Institute (now BITS, Pilani) was founded around 1950 by Prof. Schroff, further strengthening the academic landscape. During the same decade, universities like Nagpur and Sagar introduced B.Pharm programs. In 1940, BHU also began offering the first M.Pharm program**,** initially of one-year duration, which later increased to one and a half years by 1952–53. Soon after, numerous universities—including Punjab University, University of Madras, Andhra University, and SMS Medical College, Jaipur—established postgraduate and doctoral programs in pharmacy, expanding both academic and research capacities in the country.

A landmark step in elevating pharmacy research and advanced training came with the establishment of the National Institute of Pharmaceutical Education and Research (NIPER) in 1994. Designed as a premier national institute under the Government of India, NIPER paved the way for high-quality research, innovation, and specialized education. Around the same time, the BV Patel PERD Centre in Ahmedabad emerged as another key institution committed to research, professional development, and national-level scientific gatherings.

Over the last 150 years, pharmacy education in India has transformed significantly. With the dramatic expansion of pharmaceutical sciences—ranging from drug synthesis and formulation to computer-aided drug design and advanced drug delivery systems—the expectations from pharmacy graduates have broadened. For many decades after independence, the curriculum was heavily oriented toward industrial pharmacy, preparing graduates mainly for roles in production, quality control, formulation development, and marketing. However, by the 1980s and 1990s, widespread misuse of medicines, growing antimicrobial resistance, and rising adverse drug reactions highlighted the urgent need for pharmacists to take on a more patient-centric role.

This shift led to the emergence of clinical pharmacy in India, redefining the role of pharmacists from purely industrial contributors to vital members of the healthcare team. Clinical pharmacy emphasized patient compliance, rational drug use, therapeutic monitoring, and collaboration with physicians—bridging the gap between the pharmaceutical industry and patient care. This development marked a critical turning point, transforming pharmacy into a profession deeply involved in improving therapy outcomes and community health.

Today, India offers a broad spectrum of pharmaceutical education programs, including D.Pharm**,** B.Pharm**,** Pharm.D**,** M.Pharm**,** and Ph.D. The system functions under the combined regulation of the Pharmacy Council of India (PCI) and the All India Council for Technical Education (AICTE)**,** which together oversee academic standards, curriculum design, and professional competency.

HISTORY OF THE PROFESSION OF PHARMACY IN INDIA IN RELATION TO INDUSTRY AND ORGANIZATION

The development of the pharmacy profession in India is closely linked with the growth of the pharmaceutical industry and the establishment of various regulatory and professional organizations. Over the decades, pharmacy in India has evolved from a small-scale, traditional practice to a scientifically driven and globally recognized profession. This transformation took place gradually, shaped by social needs, scientific progress, industrial expansion, and government policies.

Early Developments (Before 1900s)

In ancient India, healthcare practices were primarily based on Ayurveda, Siddha, and Unani systems. Medicines were prepared by practitioners themselves using herbs, minerals, and natural materials. There was no separate professional role of a "pharmacist"; preparation and dispensing were integrated into the work of traditional healers. With the arrival of the British, western medicine entered India, introducing manufactured drugs and modern concepts of pharmacy.

Introduction of Modern Pharmaceuticals (1900–1940)

By the early 20th century, imported medicines from Europe began to dominate the Indian market. There was no regulation on drug quality, leading to widespread circulation of substandard medicines. This situation highlighted the urgent need for trained personnel in drug manufacturing and dispensing. Small drug production units began appearing in Bengal, Bombay, and Madras, marking the early industrial groundwork. A landmark step during this period was the publication of the Poison Act (1919) and the Drugs Inquiry Committee Report (1930), which drew attention to the lack of quality control and professional standards in drug handling.

Establishment of Formal Pharmacy Education (1940–1950)

Modern pharmacy education in India began in **1937**, when Professor M.L. Schroff introduced the first systematic course in pharmacy at Banaras Hindu University (BHU). This marked the beginning of professional identity for pharmacists. The rapid expansion of the drug industry during World War II further emphasized the demand for trained pharmaceutical personnel. As a result:

- Universities started diploma and degree programs in pharmacy.
- The government recognized pharmacy as a distinct profession.
- Efforts intensified to regulate drug quality within the growing pharmaceutical market.

Regulatory Framework and Professional Identity (1950–1970)

A turning point came with the Drugs Act of 1940 (later called the Drugs and Cosmetics Act, 1940), which gave the government authority to control drug import, manufacture, sale, and distribution. To standardize pharmacy practice, the Pharmacy Act, 1948 was passed, establishing:

- Pharmacy Council of India (PCI)
- State Pharmacy Councils
- Minimum standards for pharmacy education
- Mandatory registration of pharmacists

This period witnessed the formation of prominent pharmaceutical organizations such as the Indian Pharmaceutical Association (IPA) and Indian Drug Manufacturers Association (IDMA). These bodies played a crucial role in shaping ethical standards, industrial policies, and professional development.

During the 1950s and 1960s, India saw the rise of public-sector drug manufacturers like Hindustan Antibiotics Limited (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL), which strengthened self-sufficiency in bulk drug production and reduced dependence on imports.

Expansion of the Pharmaceutical Industry (1970–1990)

The next major milestone was the Indian Patents Act, 1970, which allowed only process patents for pharmaceuticals. This act helped Indian firms innovate cost-effective manufacturing methods and produce affordable generic medicines. As a result, India rapidly transformed into a major producer of bulk drugs and formulations. Pharmacy practice also diversified during this period. New roles emerged in:

- Industrial pharmacy
- Quality control and quality assurance
- Research and development
- Hospital and community pharmacy

Professional bodies continued to support this expansion through conferences, training programs, and collaboration with international organizations.

Era of Modernization and Global Recognition (1990–Present)

With economic liberalization in the early 1990s, the Indian pharmaceutical industry entered a phase of global integration. Indian companies began exporting medicines to developed markets, complying with international quality standards like WHO-GMP, US-FDA, and EU regulations. This period introduced advancements such as:

- Biotechnology and biopharmaceuticals
- Clinical research and pharmacovigilance
- Good Manufacturing Practices (GMP) and Good Pharmacy Practice (GPP)
- Use of automation in manufacturing
- Rise of multinational pharmaceutical companies in India

Pharmacy education also expanded, with the introduction of B.Pharm, M.Pharm specializations, Pharm.D, and research-oriented doctoral programs. Regulatory organizations such as PCI,

CDSCO, NPPA, and ICMR strengthened drug control, pricing mechanisms, and clinical regulations.

Role of Organizations in Shaping the Profession

Several national bodies played crucial roles in defining the structure and direction of pharmacy practice in India:

- Pharmacy Council of India (PCI): Ensures proper education and ethical standards.
- Central Drugs Standard Control Organization (CDSCO): Regulates safety, efficacy, and quality of medicines.
- Indian Pharmaceutical Association (IPA): Promotes professional development and pharmacy practice.
- Indian Drug Manufacturers Association (IDMA): Supports the interests of the pharmaceutical industry.
- National Institute of Pharmaceutical Education and Research (NIPER): Enhances research capabilities and advanced training.

Together, these organizations established a strong relationship between the pharmaceutical workforce, industrial production, academic training, and public health needs.

The history of the pharmacy profession in India reflects a steady journey from traditional healing practices to a scientifically advanced and globally respected discipline. The growth of the pharmaceutical industry, coupled with the establishment of regulatory and professional organizations, played a central role in shaping modern pharmacy. Today, India stands as one of the world leaders in pharmaceutical manufacturing, research, and healthcare delivery—an achievement built upon decades of development in pharmacy education, industry, and organizational support.

PHARMACY AS A CAREER

Pharmacy is a profession that integrates the principles of health sciences, chemical sciences, and biomedical research to ensure safe and effective use of medicinal substances. Over time, it has grown into a dynamic discipline that supports public health, pharmaceutical innovation, patient care, and clinical decision-making. As healthcare systems evolve, the pharmacist's role continues to expand from traditional dispensing to specialized functions in industry, research, and clinical practice.

1. Introduction

Pharmacy as a career involves the study of drugs—beginning from their discovery and development to their manufacturing, distribution, and therapeutic use. A pharmacist is recognized as a medication expert responsible for ensuring that patients receive appropriate, safe, and effective drug therapy. The profession appeals to students with an interest in science, problem-solving, and a desire to contribute to the improvement of community health.

Pharmacy education in India is structured to build both theoretical knowledge and practical competency. The discipline offers multiple entry points, enabling graduates to choose from a wide range of professional pathways in healthcare and the pharmaceutical sector.

2. Nature and Scope of the Profession

The scope of pharmacy extends across several domains, reflecting the diverse responsibilities associated with medicines and patient care.

a. Role in Healthcare Delivery

Pharmacists participate in drug dispensing, medication counseling, monitoring of therapy, and prevention of medication-related problems. Their involvement ensures rational drug use and contributes significantly to improved treatment outcomes.

b. Contribution to the Pharmaceutical Industry

The pharmaceutical industry relies on pharmacists for formulation development, quality testing, regulatory compliance, production supervision, and research activities. Their scientific training enables them to support manufacturing processes and maintain international quality standards.

c. Expansion into Clinical and Emerging Fields

Modern healthcare emphasizes patient-centered services. As a result, pharmacists are increasingly engaged in clinical pharmacy, pharmacovigilance, pharmacogenomics, biotechnology, and various specialized therapeutic areas.

3. Educational Pathways in Pharmacy

Pharmacy education is organized in progressive levels to develop professional competence:

a. Diploma in Pharmacy (D.Pharm)

A two-year foundational program focusing on basic pharmaceutical sciences and dispensing practices. Graduates are eligible for registration as pharmacists and can work in community or hospital pharmacy settings.

b. Bachelor of Pharmacy (B.Pharm)

A four-year undergraduate degree covering pharmaceutical chemistry, pharmaceutics, pharmacology, pharmacognosy, and related subjects. This program prepares students for careers in manufacturing, quality control, marketing, and further studies.

c. Doctor of Pharmacy (Pharm.D)

A six-year professional program with strong emphasis on clinical practice. Pharm.D graduates are trained to participate directly in patient care, therapeutic planning, and clinical decision-making within hospitals.

d. Master of Pharmacy (M.Pharm)

A two-year postgraduate program offering specialization in areas such as pharmaceutics, pharmacology, pharmaceutical chemistry, pharmacognosy, biotechnology, and regulatory affairs.

e. Doctoral Studies (Ph.D.)

Doctoral research enables students to pursue careers in scientific research, academia, and advanced pharmaceutical innovation.

4. Major Career Opportunities

a. Community Pharmacy

Community pharmacists dispense medications, provide patient counseling, maintain drug records, and contribute to public health initiatives. They play a key role in guiding patients on safe medication practices.

b. Hospital Pharmacy

Hospital pharmacists are involved in preparing medication charts, monitoring drug therapy, managing sterile preparations, and working closely with the medical team to ensure optimal treatment outcomes.

c. Pharmaceutical Industry

The industry offers opportunities in:

- Drug formulation and development
- Production and manufacturing
- Quality control and quality assurance
- Regulatory affairs and documentation
- Research and development (R&D)
- Medical writing and scientific communication

d. Clinical Pharmacy and Therapeutic Management

Clinical pharmacists evaluate prescriptions, identify drug interactions, advise on dosage adjustments, and help manage chronic disease therapy. Their contribution is vital in reducing medication errors and improving patient safety.

e. Research and Development

R&D pharmacists work on drug discovery, preclinical testing, formulation innovation, and technology-based drug delivery systems. This field is essential for developing new and improved medicines.

f. Pharmacovigilance

Pharmacovigilance professionals monitor adverse drug reactions, maintain safety databases, and assist in evaluating the risk–benefit profile of medicines throughout their lifecycle.

g. Academia

Pharmacists with advanced qualifications contribute to education and research by teaching in pharmacy colleges, guiding students, and participating in scientific investigations.

h. Government and Regulatory Services

Pharmacists are employed as Drug Inspector in drug control departments, public health institutions, armed forces medical services, and government-run hospitals. They ensure compliance with drug laws, monitor quality, and support national health programs.

i. Entrepreneurship

Pharmacists may establish community pharmacies, wholesale drug distribution firms, manufacturing units, or nutraceutical and herbal product ventures, contributing to economic and healthcare development.

Pharmacy offers a broad and rewarding career that combines scientific expertise with human service. Its diverse opportunities—ranging from patient care and research to industry and entrepreneurship—make it a versatile and respected profession. As the pharmaceutical and healthcare sectors continue to grow, the importance of pharmacists in ensuring safe, effective, and rational drug use will remain central to public health.

PHARMACOPOEIAS: INTRODUCTION AND OVERVIEW

A **pharmacopoeia** is an official book of drug standards that provides authoritative information on the quality, purity, strength, and testing methods of medicines and pharmaceutical substances. It serves as a legal and scientific reference for manufacturers, pharmacists, regulatory agencies, and healthcare professionals. Pharmacopoeias ensure that medicines supplied to the public meet established standards of safety, efficacy, and quality.

A standard pharmacopoeia contains:

- Monographs of drugs and formulations
- Standards for identity, purity, and potency
- Methods of analysis and assay
- Limits for contaminants and impurities
- Storage and packaging conditions
- Guidelines for dosage forms and excipients

Pharmacopoeias are recognized worldwide as essential documents for drug regulation and quality assurance. Every country maintains its own pharmacopoeia or adopts an internationally accepted one for regulatory purposes.

INDIAN PHARMACOPOEIA (IP): INTRODUCTION

The Indian Pharmacopoeia (IP) is the official book of standards for drugs manufactured and marketed in India. It is published by the Indian Pharmacopoeia Commission (IPC) under the Ministry of Health and Family Welfare, Government of India. The IP provides legally enforceable standards for the quality of active pharmaceutical ingredients, excipients, dosage forms, and herbal products used in the country.

The primary objectives of the IP are to:

1. Establish uniform standards for drugs in India.
2. Ensure quality, purity, and strength of medicines.
3. Provide validated analytical methods for testing.
4. Promote patient safety through quality assurance.

5. Support the pharmaceutical industry by harmonizing standards with international norms.

The first attempt to create standards for Indian drugs began during British rule, but the first official Indian Pharmacopoeia was published after independence, reflecting Indian healthcare needs and indigenous medicinal substances.

Key Features of the Indian Pharmacopoeia

- Legally binding standards for drug quality in India.
- Includes monographs on modern medicines, traditional herbal drugs, and biological products.
- Provides validated analytical procedures, including modern instrumental techniques.
- Periodically revised to meet scientific and industrial advancements.
- Harmonized with international pharmacopoeias like BP (British Pharmacopoeia) and USP (United States Pharmacopeia).

Table: All Editions of the Indian Pharmacopoeia (IP) with Years

Edition	Year of Publication	Remarks
1st Edition	**1955**	First official Indian Pharmacopoeia after independence
2nd Edition	**1966**	Expanded list of modern drugs
Addendum	**1975**	Supplement to 1966 edition
3rd Edition	**1985**	Updated analytical methods and quality standards
Addendum	**1989**	Included additional monographs
Addendum	**1991**	Updated pharmacopeial standards
4th Edition	**1996**	Major revision with new drug monographs
Addendum	**2000**	Additional standards for specific drug groups
Addendum	**2002**	Final supplement before next revision
5th Edition	**2007**	Published by Indian Pharmacopoeia Commission (IPC)
Addendum	**2008**	Added new monographs and excipients
Addendum	**2010**	Included veterinary products and biologics
6th Edition	**2010**	Major restructuring and harmonization
7th Edition	**2014**	More monographs on herbal and biotech products
Addendum	**2015**	Supplement to 2014 edition
8th Edition	**2018**	Extensive updates in analytical techniques
Addendum	**2019**	Included additional monographs
9th Edition	**2022**	Latest complete edition with modern standards

Significance of the Indian Pharmacopoeia in Pharmaceutical Practice

1. **Legal standard:** Drug manufacturers must comply with IP standards for all products sold in India.
2. **Quality assurance:** Ensures the quality and safety of pharmaceuticals across the country.
3. **Industry support:** Helps Indian pharmaceutical companies meet global regulatory expectations.
4. **Public health impact:** Prevents the circulation of substandard and counterfeit medicines.
5. **Scientific growth:** Encourages research in pharmaceutical analysis and regulatory sciences.

The Indian Pharmacopoeia plays a vital role in maintaining the quality and integrity of medicines available in India. Its regular revisions reflect the growth of the Indian pharmaceutical industry and the need for updated scientific standards. By laying down uniform and legally enforceable drug standards, the IP continues to safeguard public health and strengthen the nation's regulatory framework.

BRITISH PHARMACOPOEIA (BP): INTRODUCTION

The British Pharmacopoeia (BP) is one of the oldest and most authoritative drug standard reference books in the world. It serves as the official collection of quality standards for medicinal substances, formulations, and pharmaceutical products in the United Kingdom. Published under the authority of the Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the British Government, the BP provides legally enforceable standards that ensure the identity, purity, strength, and quality of medicines.

The BP acts as a primary regulatory tool for manufacturers, pharmacists, analysts, and healthcare professionals. It ensures that medicines supplied to the public meet uniform scientific specifications. Over the years, the BP has gained international recognition, and many countries—especially those following British regulatory traditions—adopt or reference it in their drug control systems.

Historical Background of the BP

Before the BP was established, drug standards in Britain were scattered across regional or privately prepared formularies. With the rapid expansion of medical science during the 19th century, the need for a unified national standard became urgent.

This led to:

- The merging of various pharmacopoeias used in different parts of the UK

- The formation of an official committee to create a common standard
- The publication of the First British Pharmacopoeia in 1864

Since then, the BP has been revised at regular intervals, keeping pace with scientific advancements and the introduction of new medicines.

Purpose and Functions of the British Pharmacopoeia

The BP aims to:

1. Provide legally binding drug standards for the UK and countries that recognize the BP.
2. Ensure quality and safety of active pharmaceutical ingredients, excipients, formulations, and biological products.
3. Offer validated analytical methods for identification, purity testing, assay methods, and impurity profiling.
4. Support pharmaceutical industries in maintaining global regulatory compliance.
5. Harmonize standards with international pharmacopoeias such as the European Pharmacopoeia (Ph. Eur.) and United States Pharmacopeia (USP).

The BP is revised annually today, reflecting rapid growth in pharmaceutical technology, analytical techniques, and regulatory expectations.

Key Features of the BP

- Legally enforceable standards for all medicinal substances in the UK
- Extensive monographs, including modern drugs, biologicals, vaccines, radiopharmaceuticals, herbal materials, and excipients
- Detailed analytical procedures, including chromatographic and spectroscopic methods
- Inclusion of reference standards for quality testing
- Alignment with the European Pharmacopoeia for shared monographs
- Annual publication since 2013 to keep pace with global regulatory changes

Table: All Editions of the British Pharmacopoeia (BP) with Years

Edition	Year of Publication	Remarks
1st Edition	**1864**	First unified pharmacopoeia for the United Kingdom
2nd Edition	**1867**	Revised and expanded content
3rd Edition	**1885**	Major update with new monographs
4th Edition	**1898**	Included modern analytical improvements
5th Edition	**1914**	Pre-World War I revision

6th Edition	**1932**	Included newer synthetic drugs
7th Edition	**1948**	Post-war revision with updated therapeutic agents
8th Edition	**1953**	Introduced new standards for purity
9th Edition	**1958**	Expanded pharmaceutical formulations
10th Edition	**1963**	Included more refined analytical methods
11th Edition	**1973**	Major overhaul; aligned with European standards
12th Edition	**1980**	Updated monographs and testing procedures
13th Edition	**1988**	Introduction of more modern instrumental tests
14th Edition	**1993**	Revision to meet regulatory demands
15th Edition	**1999**	Included biotechnology-based products
16th Edition	**2009**	Extensive modernization; included digital access
Annual Editions Begin	**2013 onwards**	BP becomes an *annual* publication
BP 2013	2013	First annual edition
BP 2014	2014	Updated monographs and harmonization
BP 2015	2015	Major additions in biological standards
BP 2016	2016	Included new antibiotic and excipient tests
BP 2017	2017	Expanded coverage of herbal medicines
BP 2018	2018	Increased harmonization with Ph. Eur.
BP 2019	2019	Added new radiopharmaceutical standards
BP 2020	2020	Revised impurity profiles
BP 2021	2021	Updates for COVID-related therapeutics
BP 2022	2022	Further harmonization and modernization
BP 2023	2023	Latest annual regulatory update
BP 2024	2024	Most recent edition (including digital BP Online)

Significance of the BP in Global Pharmaceutical Practice

1. **International acceptance:** Used by many Commonwealth and Asian countries.
2. **High scientific credibility:** Trusted for its rigorous and modern testing methods.
3. **Industrial relevance:** Helps pharmaceutical companies maintain global market standards.
4. **Legal importance:** Acts as a statutory reference for drug regulation.
5. **Public health impact:** Ensures that medicines meet standardized levels of quality, potency, and purity.

The British Pharmacopoeia stands as one of the world's most respected drug standard reference works. Its long history, scientific depth, and global influence make it essential for anyone involved in drug manufacturing, testing, distribution, or regulation. With annual revisions and its close

alignment with European standards, the BP continues to maintain its relevance in modern pharmaceutical practice.

UNITED STATES PHARMACOPEIA (USP)

The **United States Pharmacopeia (USP)** is an authoritative and legally recognized reference book that sets quality standards for medicines, dietary supplements, and several healthcare products used in the United States. It was first published in 1820 and has continued to evolve with advances in science, manufacturing, and regulatory needs.

The main purpose of the USP is to ensure that drugs are safe, pure, effective, and consistent in quality, regardless of where they are manufactured. It includes detailed standards for various aspects of pharmaceutical substances, such as:

- Identity (to confirm the substance is genuine)
- Strength (correct amount of active ingredient)
- Quality parameters and Purity tests
- Manufacturing requirements
- Packaging and storage recommendations
- Analytical methods and assays

USP standards are recognized under U.S. law, meaning any drug sold in the country must meet the required specifications. These norms are prepared through scientific research, expert committees, and public review processes. The USP also collaborates with global organizations to support international drug quality programs.

In addition to the main pharmacopeia, USP publishes companion texts such as the **National Formulary (NF)**, which contains monographs on excipients and pharmaceutical preparations. Together, the USP–NF serves as a trusted guide for pharmacists, manufacturers, regulators, healthcare professionals, and researchers.

EXTRA PHARMACOPOEIA (MARTINDALE'S EXTRA PHARMACOPOEIA)

The Extra Pharmacopoeia, widely known today as Martindale: The Complete Drug Reference, originated in the late 19th century as an independent and comprehensive reference text for medicines. Unlike a national pharmacopeia that provides official legal standards, Martindale serves as a scientific compendium of information on drugs used worldwide.

This text includes:

- Descriptions of pharmaceuticals from multiple nations
- Clinical uses and indications
- Pharmacological actions and adverse effects
- Dosage forms and recommended doses
- Drug interactions and toxicity details
- Therapeutic categories and brief treatment guidelines

One of its distinguishing features is that it covers both approved medicines and investigational agents, making it valuable for clinicians, pharmacists, academicians, and researchers who need an international perspective on drug therapy.

While it does not possess regulatory authority, Martindale complements official pharmacopeias by giving practical insights on drug usage, therapeutic alternatives, and comparative information across different countries. Because of its depth and reliability, it is often treated as an authoritative textbook in pharmacy and medical education.

DOSAGE FORMS: INTRODUCTION

Medicines are rarely given in their raw chemical state. To make them suitable for the patient, safe to take, and effective at the intended site of action, drugs are prepared in specific forms**,** known as dosage forms**.** A dosage form is simply the physical form in which a drug is presented to the patient, along with supporting ingredients called excipients. These forms help in safe delivery, accurate dosing, and better patient acceptance.

Why Dosage Forms Are Needed

Drugs differ in taste, solubility, stability, and action, so they cannot all be used directly as powders. Dosage forms help in:

1. **Accurate dose administration** – They ensure the patient receives the correct quantity of medicine each time.
2. **Protection of the drug substance** – Some medicines break down when exposed to air, light, or stomach acid. Dosage forms protect them until they reach the desired site.
3. **Masking unpleasant characteristics** – Bitter, irritating, or foul-smelling drugs can be coated or flavored.
4. **Controlled drug release** – Some medicines need slow, prolonged release or targeted delivery.
5. **Ease of handling and patient comfort** – Tablets, capsules, and syrups improve convenience compared to crude chemicals.

Thus, dosage forms act as vehicles for delivering medicines safely and efficiently.

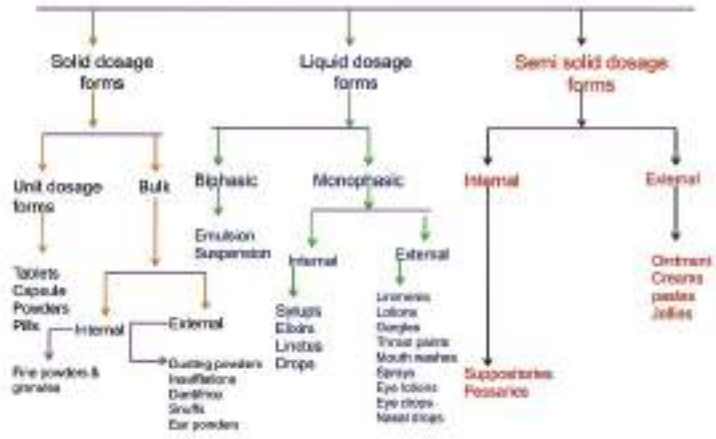
Components of a Dosage Form

Most dosage forms contain:

- **Active pharmaceutical ingredient (API)** – the actual therapeutic drug.
- **Excipients or additives** – substances that enhance stability, flow, flavor, appearance, or release properties (e.g., binders, diluents, preservatives, colorants).

Although excipients do not have therapeutic action, they are essential for product quality and performance.

CLASSIFICATION OF DOSAGE FORMS



1. Solid Dosage Forms

A. Unit Dosage Forms

These are solid preparations designed to deliver a precise, pre-measured amount of drug per unit, ensuring uniform dosing and convenient patient administration.

i) Tablets

Tablets are compressed solid units containing medicament with suitable excipients, formulated to disintegrate or dissolve in bodily fluids to release the active drug.

ii) Capsules

Capsules are solid dosage units in which drug substances are enclosed within hard or soft gelatin shells to provide tasteless swallowing and controlled release of medication.

iii) Powders

Powders are finely divided solid medicines intended for internal or external use, enabling rapid dissolution and flexibility in dosing.

iv) Pills

Pills are small spherical solid preparations traditionally made by mass rolling techniques, designed to deliver active drugs orally in swallowable form.

B. Bulk Powders

Bulk powders consist of large-quantity solid preparations supplied without unit dose division, requiring measurement before use to achieve therapeutic administration.

i) Internal Use Bulk Powders

Internal powders are orally administered fine or granulated solids dissolved or dispersed in liquid to produce systemic pharmacological action.

ii) External Use Bulk Powders

External powders are medicated fine solids applied to skin, mucosa, or cavities to deliver local therapeutic effect.

a) Dusting Powders

Dusting powders are finely micronized topical formulations applied to intact skin surfaces for protective, soothing, or antifungal actions.

b) Insufflations

Insufflations are dry powder preparations intended for direct blowing into body cavities like the ear, nose, or throat for localized therapeutic action.

c) Dentifrices

Dentifrices are powdered formulations used for cleaning, polishing, and deodorizing teeth to maintain oral hygiene.

d) Snuffs

Snuffs are nasal powder preparations inhaled to produce local or systemic pharmacological effects.

e) Ear Powders

Ear powders are finely divided medicaments instilled into the ear canal to treat infections or inflammation.

2. Liquid Dosage Forms

A. Biphasic Liquid Dosage Forms

Biphasic liquids are heterogeneous liquid systems containing two immiscible phases requiring agitation for uniform distribution before administration.

i) Emulsions

Emulsions are liquid biphasic systems where one liquid is dispersed in another immiscible liquid through an emulsifying agent to enhance stability and drug delivery.

iii) Suspensions

Suspensions are biphasic liquids wherein solid drug particles are dispersed in a liquid medium and require shaking before use for dose uniformity.

B. Monophasic Liquid Dosage Forms

Monophasic liquids are homogeneous solutions where active drugs are dissolved in suitable solvents for uniform distribution and ready absorption.

i) Internal Monophasic Liquids

These are oral solutions designed to deliver dissolved active medicaments systemically via rapid gastrointestinal absorption.

a) Syrups

Syrups are sweetened, viscous oral solutions used to enhance patient compliance while delivering dissolved medication.

b) Elixirs

Elixirs are clear, sweetened hydro-alcoholic oral solutions formulated to solubilize drugs requiring alcohol for stability or dissolution.

c) Linctus

Linctuses are viscous oral preparations intended for slow swallowing to soothe irritated mucosa, commonly used in cough management.

d) Drops

Oral drops are concentrated liquid medications administered in small measured volumes for pediatric, geriatric, or precision dosing.

ii) External Monophasic Liquids

These are liquid solutions applied externally to skin or mucosal surfaces for localized therapeutic activity.

a) Liniments

Liniments are oily or alcoholic solutions rubbed onto skin to produce counter-irritant, analgesic, or stimulant effects.

b) Lotions

Lotions are thin liquid preparations applied externally to large skin areas for soothing, protective, or medicinal purposes.

c) Gargles

Gargles are aqueous solutions used to rinse the throat and oral cavity for antiseptic, soothing, or cleansing effects.

d) Throat Paints

Throat paints are concentrated medicated solutions applied locally to throat and oral mucosa for prolonged therapeutic action.

e) Mouth Washes

Mouth washes are liquid antiseptic or cleansing formulations swished in the oral cavity to maintain hygiene and reduce microbial load.

f) Sprays

Sprays are dispersion systems administered under pressure to deliver liquid or semi-solid medication as droplets over skin or mucosa.

g) Eye Lotions

Eye lotions are sterile irrigating solutions used to cleanse or soothe ocular tissues.

h) Eye Drops

Eye drops are sterile liquid preparations instilled into the conjunctival sac for local ophthalmic therapeutic action.

i) Nasal Drops

Nasal drops are sterile aqueous or oily medications instilled into the nostrils to achieve local or systemic nasal therapy.

3. Semi-Solid Dosage Forms

A. Internal Semi-Solid Dosage Forms

These are shaped, semi-solid medicated masses intended for insertion into body cavities where they melt, soften, or dissolve to exert localized or systemic effects.

i) Suppositories

Suppositories are molded solid preparations inserted into rectal, vaginal, or urethral cavities, where they melt at body temperature to release drugs.

iii) Pessaries

Pessaries are vaginal semi-solid dosage units designed to deliver therapeutic agents for local action such as antifungal or antiseptic treatment.

b. External Semi-Solid Dosage Forms

These are semi-solid pharmaceutical preparations applied externally on skin or mucosa for localized drug delivery and protective effects.

i) Ointments

Ointments are greasy semi-solid formulations intended for topical application where they produce occlusive, emollient, or medicated effects.

ii) Creams

Creams are semi-solid emulsions with a lighter consistency designed for smooth spreading over skin to deliver active agents without excessive greasiness.

iii) Pastes

Pastes are stiff semi-solid preparations containing high solid content, applied topically to adsorb secretions and protect the skin.

iv) Jellies

Jellies are translucent, water-rich semi-solid systems applied to mucosal surfaces for soothing, lubricating, or medicated action.

PRESCRIPTION: DEFINITION AND PARTS OF A PRESCRIPTION

A **prescription** is a formal written, electronic, or verbal order given by a registered medical practitioner to a pharmacist, directing the preparation, dispensing, and administration of a particular medication for a patient. In simple terms, it acts as a communication bridge between the doctor and the pharmacist, ensuring that the patient receives the correct drug in the correct dose, form, and duration. A well-written prescription is not just a piece of paper; it reflects the doctor's clinical judgment, the patient's health needs, and the pharmacist's responsibility to dispense medicines safely and accurately. It also serves as a legal document, meaning every element written on it carries professional accountability and must comply with medical and pharmaceutical regulations.

A prescription generally consists of several important components, each serving a specific purpose to avoid confusion, ensure safety, and provide clear therapeutic instructions. Although formats may differ from hospital to hospital, the core parts remain the same because they are essential for proper understanding and execution of drug orders.

PARTS OF A PRESCRIPTION

1. Patient Information

This portion includes basic details such as the patient's name, age, sex, weight (especially important for children), and address. These details help the pharmacist verify the identity of the patient and ensure that the medication is appropriate for their age and condition. Weight is crucial in pediatric cases where dosing is often calculated on a mg/kg basis.

2. Date

The date on which the prescription is issued is always mentioned. It helps track the validity of the prescription and prevents misuse or repeated dispensing of medications such as antibiotics, controlled drugs, or expensive treatments.

3. Superscription

Traditionally, this section begins with the symbol "℞" (Rx), which is derived from the Latin word *recipe*, meaning "take thou." It indicates that the instructions written by the physician should be carried out by the pharmacist. The superscription marks the start of the doctor's therapeutic message.

4. Inscription

The inscription contains the names and quantities of the drugs prescribed. This is the core of the prescription and may include:

- The active drug or drugs
- The strength or concentration
- The dosage form (tablet, capsule, syrup, ointment, injection, etc.)

The clarity of the inscription is vital because any misinterpretation can affect the patient's treatment and safety.

5. Subscription

The subscription provides instructions to the pharmacist regarding the preparation and dispensing of the medication. In modern practice, where most medicines are commercially prepared, this section may be brief or sometimes omitted. However, in cases like compounded formulations, topical preparations, or reconstitutions, the subscription tells the pharmacist exactly how much to dispense and in what form.

6. Signa (Directions for Use)

Also known as "Sig" or "Signatura," this section carries instructions for the patient. It tells them how to take the medication—dose, route, frequency, duration, and any special precautions. For example, “Take one tablet twice daily after food” or “Apply a thin layer to the affected area at night.” This section ensures that patients use the medication correctly and safely.

7. Prescriber’s Information and Signature

This includes the doctor’s name, qualification, registration number, and signature. It is a legal requirement and confirms the authenticity of the prescription. The pharmacist must dispense medicines only when the prescription is issued by a valid registered practitioner. In case clarification is needed, the prescriber’s details allow direct communication.

8. Refill or Renewal Instructions (if applicable)

If a medication needs to be continued for a long period, the doctor may mention whether and how many times the prescription can be refilled. This prevents unauthorized repetition of therapy and ensures that the patient undergoes proper follow-up.

9. Special Instructions or Warnings

Sometimes the doctor may add specific notes such as:

- “Do not substitute”
- “For emergency use only”
- “Dispense in original container”
- Dietary or lifestyle instructions

These notes guide both the pharmacist and the patient for safe and effective use of the medicine.

A prescription is a structured and legally binding medical order that ensures patients receive safe, accurate, and appropriate treatment. Understanding the parts of a prescription helps pharmacy students recognize the clinical, legal, and therapeutic importance behind every line written by a doctor. It also highlights the pharmacist’s crucial role in checking, interpreting, and dispensing medications in a responsible manner.

HANDLING OF PRESCRIPTION

Proper handling of a prescription is one of the most important responsibilities of a pharmacist. It ensures that the patient receives the right medicine in a safe and effective manner. The process must be systematic, careful, and compliant with professional standards.

1. Receiving the Prescription

- The pharmacist first receives the prescription directly from the patient or from the hospital OPD/ward.
- The prescription is checked for completeness and clarity before proceeding.

2. Verifying Patient Information

- The pharmacist confirms the patient's name, age, gender, and any other identification details.
- This step avoids wrong dispensing and ensures that age-appropriate dosing is followed.

3. Checking Legibility and Authenticity

- The handwriting, signature, stamp, and registration number of the prescriber are checked.
- Any doubtful or unclear information must be clarified before dispensing.

4. Reviewing the Drug Order Carefully

- The name of the medicine, strength, dosage form, and dose are read attentively.
- The pharmacist checks whether the prescribed medicine is appropriate for the patient's age, condition, and diagnosis.

5. Screening for Drug-Related Problems

- The pharmacist evaluates potential drug interactions, contraindications, or allergies.
- They also check for duplications, overdoses, or underdoses.

6. Verifying Quantity and Duration

- The number of doses or quantity to be dispensed is checked to ensure it matches the prescriber's instructions.
- Any mismatch between directions and quantity is resolved before dispensing.

7. Dispensing the Medication

- The pharmacist selects the correct medicine from the shelves and cross-verifies it with the prescription.
- Expiry date, batch number, color, and appearance of the product are checked.

8. Labeling the Medication

- Clear labels with dose, timing, route, and precautions are attached.
- Children's and elderly patients' medicines are labeled more carefully as they require special attention.

9. Counseling the Patient

- The pharmacist explains how and when to take the medicine, possible side effects, and storage conditions.
- They ensure that the patient or guardian fully understands the instructions.

10. Documentation and Record Keeping

- A copy or record of the dispensed medicines is maintained, especially for antibiotics, narcotics, or high-risk drugs.
- This supports legal compliance and accountability.

Errors in Prescription

Prescription errors are mistakes that occur during writing, interpreting, or dispensing a prescription. Identifying them early helps protect patients from harm and ensures proper treatment.

1. Illegible Handwriting

- Poor handwriting may lead to misinterpretation of drug names or doses.
- This is one of the most common causes of medication errors.

2. Incomplete Patient Information

- Missing details such as age, weight, or diagnosis can lead to incorrect dosing, especially in pediatric or geriatric patients.

3. Wrong Drug Name

- Similar-sounding or look-alike drug names (e.g., Dopamine vs. Dobutamine) may be confused if not written clearly.

4. Incorrect Dose or Strength

- Errors may occur when the dose is too high, too low, or written in confusing units (mg vs. mcg).

5. Wrong Dosage Form

- Prescribing a tablet instead of a syrup for a child or a capsule instead of an injection can lead to inappropriate therapy.

6. Omission of Frequency or Duration

- Missing directions like “once daily” or “for 5 days” makes it difficult for the pharmacist and patient to follow the therapy correctly.

7. Drug Interactions

- Prescribing multiple drugs without considering major interactions, such as combining NSAIDs with anticoagulants, poses risks to patients.

8. Writing Unauthorized Abbreviations

- Use of confusing abbreviations (e.g., “OD”, “BD”, “HS”) may lead to misinterpretation and dosing errors.

9. Contraindicated Drugs

- Medicines that are unsafe for certain patients (e.g., pregnancy, kidney disease, allergy history) may be mistakenly prescribed.

10. Errors in Quantity

- Mistakes in the total quantity or number of doses can lead to either shortage or excessive supply.

11. Wrong or Missing Signature of the Doctor

- A prescription without the prescriber’s signature or stamp is not legally valid and cannot be dispensed.

12. Lack of Clear Instructions

- Directions such as “use as needed” or “take medicine properly” are vague and lead to confusion for both pharmacist and patient.

POSOLOGY: DEFINITION AND FACTORS AFFECTING POSOLOGY

Posology refers to the science and study of **drug dosage**. It deals with determining the right amount of a drug that should be administered to a patient to achieve the desired therapeutic effect without causing harm. In other words, posology explains *how much* of a medicine should be given, *how often*, and *for how long*, keeping in mind the patient’s age, weight, health condition, and several other factors. Choosing the correct dose is crucial because too small a dose may fail to produce any benefit, while too large a dose may lead to toxicity or severe side effects. Hence, posology ensures the safe and effective use of medicines.

Factors Affecting Posology

The dose of a drug cannot be the same for every patient. Several physiological, pathological, and external factors influence how much medicine a person should receive. Important factors affecting posology include:

1. Age of the Patient

- Drug doses differ for infants, children, adults, and elderly patients.
- Children require smaller doses because their organs are still developing, while older people may need dose adjustments due to reduced organ function.

2. Body Weight

- Many drugs are prescribed on a **mg/kg** basis, especially in pediatrics.
- Overweight or underweight individuals may need dose modifications to avoid toxicity or inadequate response.

3. Gender

- Biological differences may influence drug metabolism.
- Hormonal variations in females and body composition differences between males and females can sometimes require dose adjustments.

4. Physiological Condition

- Pregnancy, lactation, menstruation, and old age can affect how the body handles drugs.
- Pregnant and breastfeeding women need specially adjusted doses to protect both mother and baby.

5. Pathological Condition

- Diseases such as kidney failure, liver disorders, heart conditions, or severe infections can affect how drugs are absorbed, metabolized, or eliminated.
- Patients with organ impairment often require reduced doses.

6. Tolerance

- Repeated use of a drug can lead to tolerance, meaning the body becomes less responsive over time.
- Such patients may need higher doses to achieve the same effect.

7. Drug–Drug Interactions

- When multiple medicines are taken, they may interact with each other.
- Some drugs increase the effect of others, while some reduce it, requiring dose adjustments.

8. Route of Administration

- The dose may vary depending on whether the drug is given orally, intravenously, intramuscularly, or topically.
- For example, IV doses are usually lower because the drug enters the bloodstream directly.

9. Time of Administration

- Some medicines work better when taken before meals, after meals, or at bedtime.
- The body's biological rhythm (circadian rhythm) can change drug response.

10. Environmental Factors

- Climate, temperature, lifestyle, and occupation can influence drug response.
- For instance, people working in very hot climates may metabolize drugs faster.

11. Genetic Factors

- Genetic makeup affects how enzymes metabolize drugs.
- Some individuals are "fast metabolizers," while others are "slow metabolizers," requiring dose modifications.

12. Severity of the Disease

- Mild conditions need lower doses, whereas severe illnesses may require higher or emergency doses.

Posology is a critical field that ensures every patient receives the right amount of medication. Understanding the factors influencing dose helps healthcare professionals prescribe medicines safely, effectively, and individually tailored to each patient's condition.

PEDIATRIC DOSE CALCULATIONS

Calculating drug doses for children requires special care because their bodies handle medicines differently from adults. Factors such as organ maturity, metabolic rate, and body composition play a major role in how a drug acts in pediatric patients. To ensure safety and effectiveness, several formula-based methods are used to calculate pediatric doses. The most common approaches are based on age, body weight, and body surface area (BSA).

1. Dose Calculation Based on Age

Age-based formulas are simple and widely used when only the child's age is known. These formulas estimate the dose by comparing the child's age to an average adult dose.

1. Young's Rule (for children above 1 year)

$$\text{Child dose} = \frac{\text{Age in years}}{\text{Age} + 12} \times \text{Adult dose}$$

2. Fried's Rule (for infants below 1 year)

$$\text{Child dose} = \frac{\text{Age in months}}{150} \times \text{Adult dose}$$

3. Cowling's Rule

$$\text{Child dose} = \frac{\text{Age last birthday}}{24} \times \text{Adult dose}$$

2. Dose Calculation Based on Body Weight

Weight-based dosing is more accurate than age-based methods, especially in infants and young children. Most pediatric doses today are calculated using weight.

Formula (mg per kg body weight)

$$\text{Child dose} = \text{Dose per kg} \times \text{Body weight (kg)}$$

3. Dose Calculation Based on Body Surface Area (BSA)

BSA-based dosing is considered the **most accurate** for pediatric patients because it correlates better with metabolic activity than age or weight alone. It is used for drugs with narrow safety margins such as **anticancer medications, corticosteroids, and antibiotics**.

Step 1: Calculate BSA using the Mosteller Formula

$$\text{BSA } (\text{m}^2) = \sqrt{\frac{\text{Height (cm)} \times \text{Weight (kg)}}{3600}}$$

Step 2: Calculate the dose

$$\text{BSA } (\text{m}^2) = \sqrt{\frac{\text{Height (cm)} \times \text{Weight (kg)}}{3600}}$$

(**1.73 m²** is the average adult body surface area.)

UNIT – I: PRACTICE SET

A. Short Answer Questions

1. Define the profession of pharmacy.
2. Mention two milestones in the development of pharmacy education in India.
3. What is meant by dosage form?
4. Define prescription.
5. List the parts of a prescription.
6. What is posology?
7. Mention two factors affecting drug dose.
8. Define pharmacopoeia.
9. What is pediatric dosing?
10. Write the full form of IP, BP, and USP.

B. Long Answer Questions

1. Describe the history of pharmacy education in India.
2. Explain the growth of pharmaceutical industry in India.
3. Discuss pharmacy as a career option in India.
4. Write a detailed note on Indian Pharmacopoeia.
5. Explain classification of dosage forms with examples.
6. Describe parts of a prescription with suitable examples.
7. Explain handling of prescription in a pharmacy.
8. Discuss errors in prescription and their prevention.
9. Explain factors affecting posology.

C. Very Long Answer Questions

1. Discuss the historical development of the pharmacy profession in India with reference to education, industry, and professional organizations.
2. Explain pediatric dose calculations based on age, body weight, and body surface area with examples.
3. Describe pharmacopoeias in detail including IP, BP, USP, and Extra Pharmacopoeia.

UNIT - II

PHARMACEUTICAL CALCULATIONS: WEIGHTS AND MEASURES (IMPERIAL & METRIC SYSTEM)

In pharmacy practice, accurate measurement is the foundation of safe drug preparation and dispensing. Whether a pharmacist is compounding a formulation, calculating a dose, reconstituting a suspension, or measuring ingredients for a prescription, a precise understanding of weights and measures is essential. Traditionally, two systems have been widely used in pharmaceutical calculations—the **Imperial system** and the **Metric system**. Although the Metric system is now the global standard, knowledge of both remains important because many older prescriptions, reference books, and drug labels may still use Imperial units.

1. Metric System

The **Metric system** is the most widely accepted system in modern pharmacy due to its simplicity, decimal structure, and easy unit conversion. Units are based on multiples of 10, which reduces calculation errors.

Basic Units

- **Weight:** gram (g)
- **Volume:** liter (L)
- **Length:** meter (m)

Table: Common Metric Prefixes

Prefix	Symbol	Value
Kilo	kg	1,000 units
Hecto	h	100 units
Deca	da	10 units
Base Unit	—	1
Deci	d	0.1
Centi	c	0.01
Milli	m	0.001
Micro	µ	0.000001
Nano	n	0.000000001

Pharmacy-Relevant Conversions

- 1 kilogram (kg) = 1,000 g
- 1 gram (g) = 1,000 mg
- 1 mg = 1,000 mcg
- 1 liter (L) = 1,000 mL

- 1 mL = 1 cc (cubic centimeter)

Because of its decimal structure, converting between units simply requires shifting the decimal point.

2. Imperial System

The **Imperial system** (also called the Apothecary or British system) was historically used in medicine and pharmacy. Although it is less common today, it is still important for understanding old prescriptions, some drug concentrations, and certain household measurements.

Weight Units

- **Pound (lb)**
- **Ounce (oz)**
- **Dram (dr)**
- **Grain (gr)**

Important Conversions

- **1 pound = 16 ounces**
- **1 ounce = 8 drams**
- **1 dram = 60 grains**
- **1 grain (gr) = approximately 65 mg** (commonly approximated as 60–65 mg in practice)

Example:
5 grains ≈ 5 × 65 mg = 325 mg

This is why a common paracetamol tablet is 325 mg—it originated from the 5-grain standard.

Volume Units

- **Gallon**
- **Quart**
- **Pint**
- **Fluid ounce (fl oz)**
- **Fluid dram (fl dr)**
- **Minim**

Volume Conversions

- **1 gallon = 4 quarts**

- **1 quart = 2 pints**
- **1 pint = 16 fl oz**
- **1 fl oz = 8 fl dr**
- **1 fl dr = 60 minims**

Imperial–Metric Cross Conversions

These are widely used in pharmacy practice:

- **1 fl oz ≈ 30 mL**
- **1 pint ≈ 473 mL**
- **1 quart ≈ 946 mL**
- **1 gallon ≈ 3,785 mL (3.8 L)**
- **1 grain ≈ 65 mg**
- **1 ounce (weight) = 28.35 g**

3. Common Household Measurements Used in Pharmacy

These are often used for patient instructions:

- **1 teaspoon (tsp) = 5 mL**
- **1 tablespoon (tbsp) = 15 mL**
- **1 cup = 240 mL**

CALCULATIONS INVOLVING PERCENTAGE SOLUTIONS

Percentage solutions express the amount of solute in a 100-unit quantity of solution. They are widely used in pharmacy for preparing injections, disinfectants, oral liquids, and topical products.

Types of Percentage Solutions

(a) Weight/Volume Percent (w/v)

Used when a **solid** is dissolved in a **liquid**.
Definition:
Amount of solute (g) in 100 mL of solution.

Formula:

$$\%w/v = \frac{\text{grams of solute}}{100\ \text{mL}}$$

Example:
Prepare 250 mL of a 4% w/v NaCl solution.
4 g in 100 mL → In 250 mL = (4 × 250)/100 = **10 g NaCl**.

(b) Volume/Volume Percent (v/v)

Used when **both solute and solvent are liquids**.

Definition:
mL of solute in 100 mL solution.

Example:
Make 500 mL of 20% v/v ethanol solution:
20 mL in 100 mL → In 500 mL = 100 mL ethanol.

(c) Weight/Weight Percent (w/w)

Used mostly for **ointments, creams, gels**.

Definition:
Grams of solute in 100 g of product.

(d) Percentage Strength Conversion

- **1% w/v = 10 mg/mL**
- **1% w/w = 10 mg/g**

ALLIGATION METHOD

Alligation is a simple arithmetic tool for mixing two concentrations to get a desired concentration.

(a) Alligation Medial (Average Strength)

Used to find the **resulting concentration** after mixing two or more solutions.

Formula:

$$\text{Final strength} = \frac{\sum(\text{quantity} \times \text{strength})}{\sum \text{quantity}}$$

(b) Alligation Alternate (To find ratio of mixing)

Used to find the **proportion of two strengths** needed to prepare a required strength.

Steps:

1. Write higher strength on top left.
2. Write lower strength bottom left.
3. Write required strength in between.
4. Subtract diagonally to get the ratio.

PROOF SPIRIT

Proof spirit is a historic alcohol measurement system based on the ability of alcohol to ignite.

Definition:

"N/100 over proof" or "under proof" indicates how much stronger or weaker the alcohol is compared to standard proof spirit.

Standard Values

- **100° proof = 57.1% v/v alcohol**
- **Under-proof (U.P.)** → weaker ethanol
- **Over-proof (O.P.)** → stronger ethanol

Formula to Convert Proof Spirit to % Alcohol

$$\%\text{Alcohol} = \frac{\text{Proof degrees} \times 57.1}{100}$$

Isotonic Solutions

Isotonic solutions have the **same osmotic pressure** as body fluids (blood plasma, tears), ensuring that no cell swelling or shrinking occurs.

Two main methods are used for calculations:

4A. Method Based on Freezing Point Depression

Principle:
Body fluids freeze at **–0.52°C**.
To make a solution isotonic, its freezing point should also be reduced by **0.52°C**.

Formula:

$$\text{Amount of drug (isotonic)} = \frac{0.52 - \Delta T_f(\text{drug})}{\Delta T_f(1\%\ \text{NaCl})}$$

where **ΔTf = freezing point depression**.

4B. Molecular Weight (i-value) Method

Isotonic concentration depends on **number of particles**, not mass.

Use **osmotic coefficient (i)** and molecular weight.

Formula (Van't Hoff):

$$\text{Osmotic pressure} = i \times \frac{w}{M}$$

To make isotonic, compare with NaCl (normal saline):

$$\text{Sodium chloride equivalent (E-value)} = \frac{17}{MW/i}$$

Here, **17 = isotonic equivalent of NaCl in mg/mL**.

POWDERS — DEFINITION, CLASSIFICATION, ADVANTAGES & DISADVANTAGES

Definition

A **powder** in pharmacy is a dry, finely divided solid substance composed of uniform or non-uniform particles that may consist of a single substance or a mixture of substances. Powders are a versatile pharmaceutical dosage form used for internal (oral), external (topical) and specialty applications (e.g., insufflations, dentifrices). They may be dispensed as bulk powders (patient measures dose) or as divided powders (pre-weighed individual doses).

Classification of Powders

Powders can be classified in several practical ways used in pharmacy practice:

1. By Purpose / Use

- **Oral powders** — intended for ingestion (e.g., antacids, nutritional powders).
- **Topical/dusting powders** — applied to skin (e.g., talc-based powders, antifungal dusting powders).
- **Insufflations (nasal/pulmonary powders)** — for administration into body cavities or airways.
- **Dental powders (dentifrices)** — for dental hygiene (tooth powders).
- **Effervescent powders** — release gas when dissolved in water (e.g., effervescent analgesic formulations).
- **Aerosolizable powders** — for inhalation therapy (dry powder inhalers).

2. By Packaging / Dispensing Form

- **Bulk powders** — supplied in a container; patient measures dose with spoon or scoop.
- **Divided powders (chartulae)** — individually weighed and wrapped doses for single use.

3. By Particle Size or Fineness

- **Coarse powders** — larger particles, used where fine division is not necessary.
- **Fine powders** — very small particles; favored when rapid dissolution or uniform mixing is required.

4. By Composition / Complexity

- **Simple powders** — a single ingredient (e.g., kaolin).
- **Compound powders** — mixture of two or more ingredients (e.g., mixtures of analgesics and antacids).

5. By Method of Preparation

- **Pulverized powders** — produced by mechanical comminution (milling, grinding).
- **Crystalline or micronized powders** — produced by recrystallization or jet-milling to achieve very fine particle sizes.

Advantages of Powders

- **Flexibility of dosing:** Bulk powders allow dose adjustment; divided powders provide single convenient doses.
- **Stability:** Many drugs are more chemically stable in dry powder form than in solution.
- **Rapid onset (when appropriate):** Fine powders dissolve/disperse quickly, facilitating faster drug absorption for oral preparations.

- **Ease of swallowing (when reconstituted):** Powders can be disintegrated or dissolved into a palatable vehicle if patient cannot swallow tablets.
- **Simple manufacturing:** Many powders require less complex equipment than sterile injections or capsules.
- **Suitable for drugs not compressible:** Some active substances that cannot be tableted can be formulated as powders.
- **Topical application:** Dusting powders provide broad, uniform coverage of skin surfaces.
- **Customized combinations:** Compound powders allow combination therapy in one dose form.
- **Reduced need for preservatives:** Dry forms often do not require antimicrobial preservatives needed for aqueous liquids.

Disadvantages of Powders

- **Dose inaccuracy (bulk powders):** Patient-measured doses may be inaccurate, risking under- or overdosing.
- **Hygiene and contamination risks:** Repeated opening and handling of bulk containers can introduce contaminants and moisture.
- **Poor palatability:** Many powdered medications taste unpleasant and may be poorly accepted by children unless flavored.
- **Dusting hazards:** Fine powders can form dust clouds — risk of inhalation, irritation, or allergen exposure for patients and pharmacy staff.
- **Hygroscopicity and caking:** Many powders absorb moisture, leading to caking, reduced flowability and altered dose uniformity.
- **Dose uniformity challenges in compounding:** Ensuring homogenous mixing for low-dose potent drugs is technically demanding and requires careful technique.
- **Limited use for controlled-release needs:** Powders are generally unsuitable for sustained release unless microencapsulated.
- **Stability concerns for volatile substances:** Volatile or oxidizable substances may be lost or degraded if not properly protected.
- **Administration inconvenience for some patients:** Measuring and preparing powders at home can be inconvenient compared with ready-to-use tablets or liquids.
- **Regulatory and labeling requirements:** Divided powders must be correctly labeled and protected; topical powders must be free of contaminants such as asbestos in talc.

SIMPLE POWDERS

A simple powder contains only one medicinal or non-medicinal ingredient. It may be dispensed as a bulk powder or divided into individual doses.

Features

- Prepared by grinding or sieving a single substance.
- Used when the drug is stable and effective in plain form.
- Examples:
    - Sulfur powder (for scabies)
    - Activated charcoal powder
    - Talc powder (topical)

COMPOUND POWDERS

A compound powder contains two or more ingredients, which may be active drugs or excipients. Ingredients are mixed uniformly using techniques like trituration or geometric dilution.

Features

- Useful for combining therapeutic agents.
- Requires careful mixing to maintain uniformity.
- May be dispensed as bulk or divided powders.

Examples of Official Compound Powders

- Compound Sodium Bicarbonate Powder
- Oral Rehydration Salt (ORS) powder
- Compound Effervescent Powder
- Compound Dusting Powders (e.g., antifungal combinations)

2. Official Preparations (Examples from Pharmacopoeias)

Common Pharmacopoeial Powder Preparations

- Oral Rehydration Salts (ORS) Powder
- Senna Compound Powder
- Sulfur Sublimed Powder
- Effervescent Granular Powders
- Talc Dusting Powder
- Activated Charcoal Powder

These preparations are described in pharmacopeias such as **Indian Pharmacopoeia (IP)**, **BP**, and **USP** for identity, purity, and preparation methods.

DUSTING POWDERS

Definition

Dusting powders are finely divided powders meant for external use on skin, wounds, or mucous membranes**.**

Characteristics

- Must be free from harmful microbes**.**
- Should have smooth texture, good spreadability**,** and non-irritant nature.
- Particle size should be very fine (pass through #120 sieve).

Examples

- Antifungal dusting powders (clotrimazole + talc)
- Baby powder
- Zinc oxide + starch powder
- Sterile dusting powders used for surgical procedures

Uses

- Absorb moisture
- Reduce friction
- Prevent fungal infections
- Provide soothing effect

EFFERVESCENT POWDERS

Definition

Effervescent powders are dry mixtures containing acid and carbonate/bicarbonate that release carbon dioxide (CO_2) when dissolved in water, producing a sparkling solution.

Common ingredients

- Citric acid
- Tartaric acid
- Sodium bicarbonate

Advantages

- Improves taste
- Rapid absorption

- Useful for patients who cannot swallow tablets

Examples

- Effervescent antacids
- Effervescent pain relievers
- Vitamin C effervescent powders

EFFLORESCENT POWDERS

Definition

Efflorescent powders lose water of crystallization when exposed to air, causing powder to become damp, sticky or liquefied**.**

Examples

- Citric acid monohydrate
- Caffeine sodium benzoate
- Quinine hydrochloride
- Alum
- Sodium carbonate decahydrate

Handling

- Store in airtight containers
- Prepare freshly when needed
- Use anhydrous substitutes if possible

HYGROSCOPIC POWDERS

Definition

Hygroscopic powders absorb moisture from the atmosphere but do not liquefy completely. They become sticky or clump together.

Examples

- Calcium chloride
- Sodium hydroxide
- Phenol
- Potassium hydroxide

Handling

- Store in well-closed, moisture-resistant containers
- Use desiccants
- Mix with inert absorbents (e.g., light kaolin)

Eutectic Mixtures

Definition

A **eutectic mixture** forms when two solids mix and produce a liquid at room temperature due to a lowered melting point**.**

Examples

Common eutectic-forming substances:

- Camphor
- Menthol
- Thymol
- Phenol
- Salol

Handling Methods

To avoid liquefaction:

1. Mix with inert absorbent powders (e.g., talc, kaolin, starch).
2. Triturate separately with absorbent and then mix.
3. Package in divided doses to prevent contact.

GEOMETRIC DILUTION

Definition

Geometric dilution is a mixing technique used when combining a small quantity of potent drug with a large amount of diluent to ensure uniform distribution.

Steps

1. Mix equal amount of the drug and diluent.
2. Add an amount of diluent equal to the mixture and mix again.

3. Repeat until all diluent is incorporated.

Why It's Important

- Prevents concentration pockets.
- Ensures dose uniformity, especially for potent drugs.

Example

Mixing **1 g** of potent drug with **99 g** lactose:

- First mix 1 g drug with 1 g lactose
- Add 2 g lactose → mix
- Add 4 g lactose → mix
- Continue until all 99 g lactose is included

Liquid Dosage Forms – Introduction

Liquid dosage forms are pharmaceutical preparations in which one or more active ingredients are dissolved, suspended, or dispersed in a suitable liquid vehicle. These forms may be intended for oral, topical, parenteral, ophthalmic, otic, or nasal administration. Examples include solutions, syrups, suspensions, emulsions, elixirs, drops, lotions, and injections.

Liquids are especially useful when rapid drug action is desired, when patients have difficulty swallowing solid dosage forms, or when the drug requires a specific solvent for stability. Because the drug is already in a dispersed or dissolved state, liquid preparations can offer faster absorption and more flexible dosing options. However, they also come with certain limitations related to stability, storage, and microbial contamination.

Advantages of Liquid Dosage Forms

1. Easy to Swallow

Liquids are ideal for children, elderly patients, bedridden individuals, and those with dysphagia, eliminating the difficulty of swallowing tablets or capsules.

2. Faster Absorption and Onset of Action

Drugs in solution do not require disintegration, so they are absorbed more rapidly, providing quicker therapeutic effects compared to solid forms.

3. Flexible and Accurate Dose Adjustment

Doses can be easily measured using spoons, droppers, or cups, allowing dose flexibility especially useful in pediatric, geriatric, or individualized therapy.

4. Suitable for Drugs That Are Difficult to Compress

Some drugs cannot be formulated into tablets due to poor compressibility or instability; liquids provide an alternative dosage form.

5. Masking of Bitter or Unpleasant Taste

Vehicles such as syrups, flavored solutions, and suspensions can help improve palatability, enhancing patient compliance.

6. Better for Drugs Requiring Specific Solvents

Oil-soluble or alcohol-soluble drugs can be incorporated into appropriate liquid vehicles that would be impractical in solid dosage forms.

7. Versatility of Route

Liquid dosage forms can be used for oral, topical, parenteral, ophthalmic, otic, inhalation, and nasal routes, increasing therapeutic application.

Disadvantages of Liquid Dosage Forms

1. Poor Stability

Liquids are more prone to chemical degradation (hydrolysis, oxidation), physical instability (sedimentation, flocculation), and microbial growth, reducing shelf life.

2. Bulky and Less Portable

Liquid bottles are heavier and more fragile than tablets or capsules, making them less convenient for travel or storage.

3. Requirement of Preservatives

Aqueous liquid preparations often need antimicrobial preservatives to prevent contamination, adding complexity and cost.

4. Dose Inaccuracy

Doses measured using household spoons may be inaccurate; improper measuring could lead to underdose or overdose, especially in children.

5. Unpleasant Taste or Odor

Some drugs have strong tastes or odors that are difficult to mask completely, reducing patient compliance.

EXCIPIENTS USED IN THE FORMULATION OF LIQUID DOSAGE FORMS

Excipients play a crucial role in the stability, safety, and acceptability of liquid medicines. They do not have therapeutic activity, but they support the drug in dissolving, stabilizing, preserving, and improving patient compliance. Each excipient is selected based on the drug's physicochemical properties and the purpose of the formulation.

1. Solvents / Vehicles

These are the medium in which the drug is dissolved or dispersed.
Common examples:

- Purified water – most frequently used vehicle.
- Alcohol (ethanol) – used for poorly water-soluble drugs.
- Propylene glycol and Glycerin – used as co-solvents to improve solubility and stability.
- Aromatic waters – flavored waters used in dilute solutions.

2. Co-solvents

Co-solvents increase the solubility of drugs that have partial solubility in water.
Examples:

- Propylene glycol
- PEG-400
- Ethanol

They reduce the polarity of water and help dissolve lipophilic drugs.

3. Buffers

Buffers maintain the **pH** of the solution, ensuring stability, solubility, and patient safety.
Examples:

- Citrate buffer
- Phosphate buffer
- Acetate buffer

Proper pH also increases preservative effectiveness.

4. Preservatives

Preservatives prevent the growth of microorganisms in aqueous solutions, especially in multi-dose bottles.
Common preservatives:

- Parabens (methylparaben, propylparaben)
- Benzalkonium chloride
- Chlorocresol
- Sodium benzoate

They must be safe, non-irritating, and effective over a wide pH range.

5. Antioxidants

These excipients prevent oxidation of drug molecules which can cause discoloration or loss of potency.
Examples:

- Ascorbic acid
- Sodium metabisulfite
- Butylated hydroxytoluene (BHT)
- Butylated hydroxyanisole (BHA)

Antioxidants are usually combined with chelating agents for better protection.

6. Chelating Agents

Chelating agents bind trace metals that catalyze oxidation reactions.
Example:

- EDTA (ethylenediaminetetraacetic acid)

They are especially useful in formulations containing metal-sensitive drugs.

7. Sweetening Agents

These improve palatability, especially for pediatric formulations.
Examples:

- Sucrose
- Sorbitol
- Saccharin sodium
- Aspartame

Sweeteners are selected based on caloric value and patient group (e.g., diabetics).

8. Flavoring Agents

Flavoring agents mask unpleasant taste and improve patient acceptance.
Examples:

- Orange, lemon, mint, vanilla, raspberry flavors.

9. Coloring Agents

Colorants make the product visually appealing and help in identification. Only approved food-grade colors are used (e.g., FD&C dyes).

10. Viscosity Modifiers / Thickening Agents

These agents increase the viscosity of the preparation to improve mouthfeel and suspend particles.
Examples:

- Methylcellulose
- Carboxymethylcellulose
- Xanthan gum
- Acacia

They provide stability to suspensions and prevent rapid settling.

11. Surfactants

Surfactants reduce surface tension and help solubilize hydrophobic drugs or stabilize emulsions.
Examples:

- Polysorbate 80 (Tween 80)
- Span 20
- Sodium lauryl sulfate

They improve wetting and dispersion.

SOLUBILITY ENHANCEMENT TECHNIQUES

Many drugs have poor water solubility, which limits their absorption and therapeutic effectiveness. Various techniques are applied to increase solubility and bioavailability.

1. Use of Co-solvents

Co-solvents like ethanol, propylene glycol, and PEG decrease the polarity of water and help dissolve lipophilic drugs.

2. pH Adjustment

For weak acids or weak bases, adjusting the pH to a more soluble form can significantly enhance solubility.
Example: Weak acids dissolve better at high pH; weak bases at low pH.

3. Surfactants (Micellar Solubilization)

Surfactants form **micelles** that entrap hydrophobic drugs inside their core, improving aqueous solubility.
Example: Polysorbates, sodium lauryl sulfate.

4. Complexation

Complexation involves forming complexes between the drug and complexing agents. Example:

- **Cyclodextrins** form inclusion complexes with poorly soluble drugs.
  These complexes increase solubility and stability.

5. Hydrotropy

Hydrotropes are ionic organic compounds that enhance solubility by altering solvent structure. Examples:

- Sodium benzoate
- Sodium salicylate

Hydrotropy is useful for moderately water-insoluble drugs.

6. Salt Formation

Converting a poorly soluble drug into a salt form can drastically improve solubility. Example:

- Diclofenac sodium is more soluble than diclofenac acid.

7. Particle Size Reduction

Reducing particle size increases surface area and improves dissolution rate. Techniques include:

- Micronization
- Nanonization
- Milling

Smaller particles dissolve faster in aqueous solutions.

8. Use of Co-precipitates and Solid Dispersions

Poorly soluble drug is dispersed in a water-soluble carrier (e.g., PEG). This enhances wetting, reduces crystallinity, and improves solubility.

9. Use of Emulsions and Microemulsions

Oil-soluble drugs can be incorporated into an oil phase and dispersed in water using emulsifying agents. Microemulsions offer thermodynamic stability and very small droplet size, increasing drug solubility.

10. Heating

Mild heating can improve the dissolution of heat-stable drugs. However, it must be carefully controlled to avoid degradation.

UNIT – II: PRACTICE SET

A. Short Answer Questions

1. Define pharmaceutical calculations.
2. What is the metric system?
3. Define percentage solution.
4. What is alligation?
5. Define proof spirit.
6. What is isotonic solution?
7. Define powder dosage form.
8. What are dusting powders?
9. Define efflorescent substances.
10. What is geometric dilution?

B. Long Answer Questions

1. Explain imperial and metric systems of weights and measures.
2. Describe calculations involving percentage solutions with examples.
3. Explain alligation method with numerical problems.
4. Discuss isotonic solutions based on freezing point depression.
5. Define powders and explain their classification.
6. Explain advantages and disadvantages of powders.
7. Describe effervescent powders with examples.
8. Explain eutectic mixtures and their pharmaceutical importance.
9. Describe advantages and disadvantages of liquid dosage forms.

C. Very Long Answer Questions

1. Discuss pharmaceutical calculations involving percentage strength, proof spirit, and isotonic solutions with suitable examples.
2. Describe simple and compound powders, official preparations, and methods of dispensing powders.
3. Explain excipients used in liquid dosage forms and solubility enhancement techniques in detail.

UNIT - III

MONOPHASIC LIQUIDS: DEFINITIONS AND PREPARATIONS

Monophasic liquids are single-phase liquid dosage forms in which the drug is completely dissolved in a suitable solvent system. These preparations appear uniform throughout and do not require shaking before use. They are designed for internal, external, or mucosal administration, depending on their purpose and composition.

Monophasic liquids offer benefits such as easy dose adjustment, rapid absorption, and suitability for patients who have difficulty swallowing solid dosage forms. They may contain additional excipients like preservatives, flavors, colors, viscosity enhancers, and stabilizers to improve their safety, stability, and acceptability.

GARGLES

Gargles are aqueous liquid preparations intended to be used in the throat and oral cavity by holding the solution in the throat, swishing it around, and then expelling it without swallowing**.**

They are mainly used for:

- Relieving throat irritation and inflammation
- Reducing microbial load in mouth and throat
- Providing soothing or antiseptic action
- Managing infections such as pharyngitis or tonsillitis

Gargles are usually supplied as:

- Ready-to-use solutions, or
- Concentrated forms that must be diluted with warm water before use.

Preparation of Gargles

The preparation of a gargle involves dissolving the active ingredient in a suitable aqueous vehicle, adjusting pH, and adding excipients that enhance stability, taste, and patient compliance.

i. Selection of Ingredients

- **Active ingredients:** antiseptics (povidone-iodine, chlorhexidine), analgesic/anti-inflammatory agents, astringents, or soothing substances.
- **Vehicle:** purified water is commonly used.
- **Flavoring and sweetening agents:** to reduce bitterness and improve acceptability.
- **Colorants:** food-grade colors may be added for appearance.

- **Preservatives:** used when the formulation is aqueous and stored for long periods (e.g., sodium benzoate, parabens).
- **pH adjusters:** citric acid, sodium citrate, or other buffers to maintain throat-friendly pH.

ii. Method of Preparation

a) **Dissolve the active drug**

- The active ingredient is dissolved in a portion of purified water.
- If poorly soluble, a co-solvent like glycerin or alcohol may be used in small quantities.

b) **Add auxiliary agents**

- Sweeteners and flavoring agents are added to improve taste.
- Colorants are added in a very small quantity if needed.

c) **Adjust the pH**
- pH is adjusted using buffering agents to ensure stability and reduce throat irritation.

d) **Make up the volume**
- The solution is diluted with purified water to the final desired volume.

e) **Filtration**
- The entire preparation is filtered to remove particulate matter, ensuring clarity.

f) **Packaging**
- The solution is filled into amber or fluted bottles to protect from light.
- Concentrated gargles are labeled with dilution instructions (e.g., “Dilute with equal volume of warm water before use”).

g) **Labeling**

- **“**For gargling only. Do not swallow.**”**
- Storage instructions: “Store in a cool, dry place.”

MOUTHWASHES

Mouthwashes are clear, flavored, aromatic liquid preparations intended for cleaning, deodorizing, and refreshing the oral cavity**.** They are used by swirling the liquid inside the mouth and then expelling it. Mouthwashes help reduce microbial load, maintain oral hygiene, control plaque, and provide a pleasant taste and breath freshness.

They may contain:

- Antiseptics
- Astringents
- Deodorizing agents
- Anti-plaque agents
- Flavors and sweeteners

Mouthwashes are not intended for swallowing and are mainly used for cosmetic or medicinal purposes.

Preparation of Mouthwashes

The preparation of a mouthwash focuses on solubilizing active ingredients, improving taste, and maintaining clarity and stability.

1. Selection of Ingredients

a. Active Ingredients

Based on the intended therapeutic effect:

- **Antiseptics:** chlorhexidine gluconate, cetylpyridinium chloride
- **Anti-plaque agents:** triclosan
- **Astringents:** zinc salts
- **Deodorizing agents:** essential oils like eucalyptus, peppermint
- **Fluoride salts:** for anti-caries effect

b. Vehicles

- **Purified water** → main solvent
- **Co-solvents** (if needed): ethanol, glycerin, or propylene glycol to dissolve flavors or essential oils.

c. Excipients

- **Sweeteners:** sorbitol, saccharin sodium
- **Flavors:** mint, menthol, clove, lemon
- **Colorants:** permitted food-grade dyes
- **Preservatives:** sodium benzoate, parabens
- **Surfactants:** to solubilize essential oils and ensure clarity

2. Method of Preparation

Step 1: Dissolution of Ingredients

- Water-soluble ingredients (e.g., antiseptics, sweeteners, fluoride salts) are dissolved in purified water.
- Alcohol or glycerin is used to dissolve flavoring oils separately.

Step 2: Mixing of Solutions

- The alcoholic solution containing flavors is added **slowly** to the aqueous phase with continuous stirring to avoid precipitation or turbidity.
- Surfactants may be added to maintain clarity and solubilize essential oils.

Step 3: Adjusting pH

- pH is adjusted to a suitable level (usually around neutral or slightly acidic) to ensure stability, comfort, and microbial control.

Step 4: Make Up the Final Volume

- The solution is diluted to the required volume using purified water.

Step 5: Filtration

- The finished solution is filtered through a fine filter to obtain a **clear and particle-free mouthwash**.

Step 6: Packaging

- Mouthwashes are filled into **fluted, colored, or transparent bottles** with tight closures.
- Large volume preparations may be filled in plastic bottles for ease of use.

3. Labeling Requirements

- "**For oral rinsing only. Do not swallow.**"
- Directions for use, such as rinsing for 30 seconds.
- Storage instructions: "Store in a cool, dry place."

THROAT PAINTS

Throat paints are viscous, concentrated liquid preparations intended for direct application to the mucous membranes of the throat**.** They adhere to the surface and provide prolonged local action**,** usually to relieve pain, irritation, or infection.

They are applied using a cotton swab or applicator**.**

Preparation

Ingredients

- **Active agents:** antiseptics (iodine, phenol), analgesics, astringents
- **Base:** glycerin (provides viscosity and adhesion)
- **Co-solvents:** water or alcohol
- **Colorants/flavors:** optional
- **Preservatives:** if water is present

Method

1. Dissolve the active ingredient in a small quantity of alcohol or water.
2. Add glycerin to obtain the required thickness and adhesiveness.
3. Mix thoroughly until uniform.
4. Adjust the volume with glycerin or water.
5. Filter (if required) to remove impurities.
6. Pack in amber-colored bottles with “For external use only”.

EAR DROPS (OTIC SOLUTIONS)

Ear drops are sterile liquid preparations intended to be instilled into the external auditory canal**.** They may be used for:

- Treating infections
- Removing earwax
- Reducing inflammation or pain

Preparation

Ingredients

- **Drug:** antibiotics, analgesics, antifungals, wax-softening agents
- **Vehicle:** purified water, glycerin, propylene glycol, or oils

- **Stabilizers:** antioxidants for oily bases
- **Preservatives:** for multi-dose containers
- **Buffers:** to maintain comfortable pH

Method

1. Dissolve or disperse the drug in the chosen vehicle.
2. Adjust pH to reduce irritation.
3. Add preservatives and stabilizers.
4. Sterilize by filtration (aqueous bases) or heat (oil bases).
5. Fill in sterile, dropper-type containers.

Label

- "**For ear use only**".
- Warm before use (if needed) to avoid dizziness.

NASAL DROPS

Nasal drops are aqueous or oily sterile solutions intended for instillation into the nasal cavity to relieve congestion, deliver medications, or moisturize mucosa.

Common drugs include decongestants (xylometazoline), antihistamines, antiseptics, and lubricants.

Preparation

Ingredients

- **Drug:** decongestant, antihistamine, antiseptic
- **Vehicle:** sterile water or oil
- **Isotonicity agents:** sodium chloride to avoid mucosal irritation
- **Buffers:** maintain physiological pH
- **Preservatives:** for multi-dose packs

Method

1. Dissolve the drug in sterile water or oil base.
2. Adjust isotonicity using NaCl.
3. Add preservatives and buffers.
4. Sterilize by membrane filtration.
5. Fill aseptically into sterile nasal-drop containers.

Label

- "**For nasal use only**".
- Do not share with others to avoid cross-infection.

ENEMAS

Enemas are liquid preparations introduced into the rectum for either therapeutic (relief of constipation, drug delivery) or diagnostic (bowel cleansing before procedures) purposes.

They may be aqueous, oily, or emulsion-based depending on the requirement.

Preparation

Ingredients

- **Drug or cleansing agent:** e.g., sodium phosphate (purgative), soap solution (evacuant), anti-inflammatory drugs
- **Vehicle:** warm water, oils (olive oil), glycerin
- **Lubricants:** aid administration
- **Stabilizers:** if emulsion-type

Method

1. Dissolve or disperse the active substance in warm purified water or oil.
2. Add surfactants or lubricants if required.
3. Mix thoroughly to ensure uniformity.
4. Filter aqueous enemas to remove particles.
5. Fill into enema bags, squeezable bottles, or disposable plastic units.

Label

- **"**For rectal use only**".**
- Use immediately after opening.

SYRUPS

Syrups are concentrated, viscous, sweetened liquid preparations that contain a high proportion of sugar, most commonly sucrose, dissolved in purified water. They may be:

- Medicated syrups, containing active pharmaceutical ingredients
- Flavored syrups, used as vehicles or sweetening agents

The high sugar concentration (around 66–67% w/w sucrose) acts as a preservative and provides a pleasant taste, making syrups particularly suitable for children and elderly patients**.**

Preparation of Syrups

Syrups can be prepared by several methods depending on the nature of ingredients and the required clarity, stability, and flavor profile.

1. Methods of Preparation

A. Solution with Heat

This is the most common method. Sugar is dissolved in water using gentle heating.

Steps:

1. Heat purified water in a clean vessel.
2. Add sugar gradually with continuous stirring.
3. Maintain low heat until the sugar dissolves completely.
4. Cool the solution.
5. Add heat-sensitive substances (flavors, drugs, preservatives) after cooling.
6. Filter to ensure clarity.
7. Make up the final volume with purified water.

Note: High temperatures must be avoided to prevent caramelization of sugar.

B. Solution without Heat (Cold Process)

Used for heat-sensitive drugs or ingredients.

Steps:

1. Sugar is placed in water and allowed to dissolve gradually with stirring.
2. This takes longer but prevents decomposition of sensitive components.
3. After complete dissolution, flavors and drugs are added.
4. The solution is filtered and made up to volume.

C. Percolation Method

Used when syrup contains medicinal substances that need extraction.

Steps:

1. Place sugar or drug-containing materials in a percolator.
2. Purified water is added to extract the soluble components.
3. Collect the percolate and adjust the sugar concentration.
4. Filter and add flavoring agents if required.

D. By Addition of Medicinal Substances

Sometimes medicated syrups are made by adding extracts or tinctures directly to simple syrup.

Steps:

1. Prepare simple syrup.
2. Add the medicinal tincture or extract.
3. Remove insoluble matter by filtration or clarification agents.

ELIXIRS

Elixirs are clear, sweetened hydroalcoholic solutions containing one or more active ingredients. They are designed for oral administration and are particularly useful for drugs that are poorly soluble in water but soluble in alcohol**.**

Elixirs are less sweet and less viscous than syrups, making them easier to swallow for adults and children.

Preparation

Ingredients

- **Active drug(s):** soluble in water or alcohol
- **Vehicle:** mixture of purified water and ethanol (hydroalcoholic base)
- **Sweeteners:** sucrose, sorbitol, or glycerin
- **Flavors:** peppermint, orange, cherry
- **Colorants:** optional, food-grade dyes
- **Preservatives:** parabens, sodium benzoate
- **Co-solvents:** propylene glycol or glycerin for solubility

Method

1. Dissolve alcohol-soluble ingredients in ethanol.
2. Dissolve water-soluble ingredients in purified water separately.
3. Combine the two solutions slowly with constant stirring to avoid precipitation.
4. Add sweeteners, flavors, colorants, and preservatives.

5. Adjust volume with water or ethanol as required.
6. Filter to ensure clarity and fill in well-closed bottles.

LINIMENTS

Liniments are liquid or semi-liquid preparations applied to the skin with rubbing. They are intended to provide local stimulation, analgesic, counter-irritant, or warming effect to muscles and joints.

Liniments are for external use only.

Preparation

Ingredients

- **Active drugs:** counter-irritants (camphor, menthol), analgesics (salicylates), essential oils
- **Vehicle/Base:** alcoholic solutions, oils (olive oil, mineral oil), or combinations
- **Additives:** stabilizers or antioxidants for oily liniments

Method

1. Dissolve or disperse the active ingredients in the selected base.
2. Ensure uniform mixing of oils and alcohol if both are used.
3. For suspension-type liniments, triturate and mix thoroughly.
4. Filter if needed to remove insoluble particles.
5. Fill in dark or opaque bottles with labeling “For external use only.”

LOTIONS

Lotions are liquid preparations intended for external application without rubbing. They are used to soothe, protect, cleanse, or medicament the skin. Unlike liniments, lotions are typically **less viscous** and are applied by gentle spreading rather than vigorous rubbing.

Lotions can be aqueous, alcoholic, or emulsions.

Preparation

Ingredients

- **Active agents:** antiseptics, astringents, soothing agents (calamine, zinc oxide)
- **Vehicle:** purified water, alcohol, or combination
- **Suspending agents:** if particles are present (e.g., for calamine lotion)

- **Additives:** preservatives, stabilizers, and sometimes colorants or fragrances

Method

1. Dissolve water-soluble drugs in purified water.
2. If the preparation contains insoluble powders (e.g., calamine), triturate with a little water or glycerin to form a smooth paste.
3. Add alcohol or co-solvents if required and mix thoroughly.
4. Adjust volume with purified water to achieve the final concentration.
5. Filter to remove lumps or impurities.
6. Fill into **well-labeled bottles** with instructions: “Shake well before use” if a suspension.

BIPHASIC LIQUIDS – SUSPENSIONS

A suspension is a biphasic liquid dosage form in which finely divided, insoluble solid particles are dispersed in a liquid medium (usually water, but sometimes oil or other suitable vehicles). Unlike solutions, the dispersed particles do not dissolve and may settle over time, forming a sediment that can be redistributed upon shaking**.**

Suspensions are particularly useful for drugs that are poorly soluble in water, allowing them to be administered orally, topically, or parenterally.

Advantages of Suspensions

1. **Improved Bioavailability**
    - Drugs that are poorly soluble in water can be administered effectively, enhancing **therapeutic action**.
2. **Ease of Swallowing**
    - Suitable for **children, elderly, and patients with difficulty swallowing tablets or capsules**.
3. **Flexibility in Dosing**
    - Dose can be **adjusted accurately** using calibrated spoons or syringes, which is useful for pediatrics and geriatrics.
4. **Masking Unpleasant Taste**
    - Flavoring agents can be incorporated to **mask the bitterness or odor** of active drugs.
5. **Stability of Drug**
    - Some drugs unstable in solution form are **more stable in suspension**, as the drug remains in solid state rather than dissolved.
6. **Prolonged Action**

- Suspensions can be formulated to provide **controlled or sustained release** of the drug.

Disadvantages of Suspensions

1. **Physical Instability**
   - Particles may settle quickly, leading to **caking** that is difficult to redisperse.
2. **Dose Inaccuracy**
   - Improper shaking before administration may result in **uneven dosing**, especially if sediment forms at the bottom.
3. **Microbial Contamination**
   - Aqueous suspensions are prone to **microbial growth**, requiring preservatives.
4. **Complex Formulation**
   - Requires careful **particle size control, viscosity adjustment, and stabilizer addition** to maintain uniformity.
5. **Shorter Shelf Life**
   - Compared to solutions, suspensions often have a **limited storage period** due to sedimentation and potential chemical degradation.
6. **Unpleasant Mouthfeel**
   - Coarse particles may produce **gritty texture** and reduce patient compliance if not properly formulated.

Classification of Suspensions

Suspensions can be classified based on **route of administration, particle size, or intended use**.

A. Based on Route of Administration

1. **Oral Suspensions** – e.g., antacids, antibiotics
2. **Topical Suspensions** – e.g., calamine lotion
3. **Parenteral Suspensions** – e.g., injectable antibiotics
4. **Ophthalmic Suspensions** – e.g., eye drops containing insoluble drugs

B. Based on Particle Size

1. **Coarse Suspensions** – particle size > 10 µm
2. **Fine Suspensions** – particle size 1–10 µm
3. **Colloidal Suspensions** – particle size < 1 µm

C. Based on Flocculation

1. **Flocculated Suspensions** – particles form loose aggregates (flocs) that **settle rapidly but are easily redispersed**
2. **Deflocculated Suspensions** – particles settle slowly, forming **compact sediment that may be hard to redisperse**

Preparation of Suspensions

The goal is to **disperse insoluble solid particles uniformly** in a liquid medium and prevent caking or aggregation.

Steps in Preparation

1. **Particle Size Reduction**
    - Use trituration, milling, or micronization to reduce particle size for uniform dispersion.
2. **Wetting of Particles**
    - Hydrophilic or lipophilic drugs are wetted with suitable agents:
        - Water, glycerin, alcohol, or surfactants to prevent clumping.
3. **Dispersion**
    - Slowly add particles to the vehicle with continuous stirring to ensure **even distribution**.
4. **Addition of Suspending Agents**
    - Increase viscosity and maintain uniform suspension using:
        - Natural gums (acacia, tragacanth)
        - Cellulose derivatives (CMC, methylcellulose)
        - Synthetic polymers (polyvinylpyrrolidone, carbomers)
5. **pH Adjustment**
    - Stabilize drug and excipients and enhance compatibility.
6. **Preservatives and Flavoring**
    - Protect against microbial growth (sodium benzoate, parabens)
    - Mask unpleasant taste for oral use
7. **Filtration and Packaging**
    - Remove large particles or impurities; package in **well-closed bottles**.

Flocculated and Deflocculated Suspensions

A. Flocculated Suspensions

- **Definition:** Particles loosely aggregate into flocs that **settle rapidly** but do **not form hard cake**.
- **Advantages:** Easy to redisperse, uniform dosing.

- **Appearance:** Often slightly turbid due to floc formation.
- **Stabilization:** Use electrolytes, polymers, or surfactants to promote flocculation.

B. Deflocculated Suspensions

- **Definition:** Particles remain separate and settle slowly, forming **compact sediment (cake)** that is difficult to redisperse.
- **Disadvantages:** Risk of caking, uneven dosing.
- **Appearance:** Clear supernatant, slowly settling particles.
- **Stabilization:** Increase viscosity using suspending agents to prevent rapid sedimentation and caking.

Stability Problems of Suspensions

Suspensions are prone to several physical and chemical stability issues:

1. **Sedimentation**
    - Particles settle over time; rapid sedimentation may lead to caking.
2. **Caking**
    - Formation of hard, compact sediment that cannot be easily redispersed.
3. **Aggregation / Flocculation**
    - Uncontrolled flocculation may cause uneven particle size and sedimentation.
4. **Microbial Growth**
    - Aqueous suspensions are prone to contamination without preservatives.
5. **Chemical Degradation**
    - Drug may hydrolyze or oxidize in the aqueous medium.
6. **Ostwald Ripening**
    - Larger particles grow at the expense of smaller ones, affecting uniformity.

Methods to Overcome Stability Problems

1. **Use of Suspending Agents**
    - Increase viscosity to slow sedimentation (e.g., CMC, xanthan gum).
2. **Controlled Flocculation**
    - Add electrolytes or surfactants to promote **reversible flocculation**.
3. **Wetting Agents**
    - Improve particle dispersion and prevent clumping.
4. **pH Adjustment and Buffers**
    - Maintain chemical stability and solubility.
5. **Preservatives**
    - Prevent microbial growth (e.g., parabens, sodium benzoate).

6. **Particle Size Reduction**
    - Smaller particles settle slowly, reducing caking.
7. **Proper Packaging**
    - Use wide-mouth bottles and label instructions to shake before use**.**

BIPHASIC LIQUIDS – EMULSIONS

An emulsion is a biphasic liquid dosage form in which one immiscible liquid is dispersed as small droplets (dispersed phase) throughout another liquid (continuous phase).

- The continuous phase surrounds the dispersed droplets.
- Emulsions are stabilized using emulsifying agents to prevent coalescence of droplets.

Example: Oil-in-water (O/W) and water-in-oil (W/O) emulsions.

Uses of emulsions:

- Oral administration of oils (cod liver oil)
- Topical application (creams, lotions)
- Parenteral nutrition (lipid emulsions)

Classification of Emulsions

Emulsions are primarily classified based on the **nature of the dispersed and continuous phases**, **therapeutic use**, or **route of administration**.

A. Based on Dispersed and Continuous Phase

1. **Oil-in-Water (O/W) Emulsion**
    - Oil droplets dispersed in water.
    - **Examples:** Milk, linseed oil emulsion.
    - Water is the external phase; easy to wash off; suitable for oral administration.
2. **Water-in-Oil (W/O) Emulsion**
    - Water droplets dispersed in oil.
    - **Examples:** Cold creams, certain ointments.
    - Oil is the external phase; greasy; more suitable for topical application.

B. Based on Route of Administration

1. **Oral Emulsions** – e.g., cod liver oil emulsion
2. **Topical Emulsions** – creams, lotions
3. **Parenteral Emulsions** – intravenous lipid emulsions

C. Based on Physical Stability

1. **Macroemulsions** – droplet size 0.1–100 µm, appear cloudy
2. **Microemulsions** – droplet size 0.01–0.1 µm, appear transparent
3. **Nanoemulsions** – droplet size <0.1 µm, enhanced stability

Emulsifying Agents

Emulsifying agents are **substances that stabilize emulsions by reducing interfacial tension** between the two immiscible liquids and forming a protective film around dispersed droplets.

Classification of Emulsifying Agents

1. **Natural Emulsifiers**
    - **Acacia (gum arabic):** O/W emulsions; used in oral and topical formulations
    - **Tragacanth, Agar, Pectin:** Stabilizers in pharmaceutical emulsions
2. **Semi-Synthetic Emulsifiers**
    - **Methylcellulose, Carboxymethylcellulose (CMC):** Increase viscosity; stabilize O/W emulsions
3. **Synthetic Emulsifiers**
    - **Span 20, Span 80, Tween 20, Tween 80:** Non-ionic surfactants for O/W or W/O emulsions
    - **Sodium lauryl sulfate, Cetyltrimethylammonium bromide:** Ionic surfactants
4. **Finely Divided Solids (Pickering Emulsions)**
    - **Colloidal silica, bentonite, magnesium hydroxide:** Stabilize emulsions by forming a physical barrier around droplets

Tests for Identification of Type of Emulsion

Determining whether an emulsion is **oil-in-water (O/W)** or **water-in-oil (W/O)** is important for stability, use, and patient acceptability.

1. Dilution Test

- An emulsion can be diluted **only with its continuous phase**.
- If the emulsion can be diluted with water → **O/W emulsion**.
- If it can be diluted with oil → **W/O emulsion**.

2. Dye Solubility Test

- A **water-soluble dye** (e.g., methylene blue) is added.
    - Uniform blue color → **O/W emulsion**.

- An **oil-soluble dye** (e.g., Sudan III) is added.
  - Uniform red color → **W/O emulsion**.

3. Electrical Conductivity Test

- Water conducts electricity; oil does not.
- If the emulsion conducts electricity → **O/W emulsion**.
- If it does not conduct electricity → **W/O emulsion**.

4. Filter Paper Test

- A drop of emulsion is placed on filter paper.
- Spreading with a water ring → **O/W emulsion**.
- Greasy spot without spreading → **W/O emulsion**.

5. Cobalt Chloride Test

- Cobalt chloride paper turns **blue to pink** in the presence of water.
- Color change indicates **O/W emulsion**.

Methods of Preparation of Emulsions

1. Dry Gum Method (Continental Method)

- Suitable for **O/W emulsions** using acacia.

Steps:

1. Triturate gum with oil in a dry mortar.
2. Add water all at once (in 4:2:1 ratio of oil:water:gum).
3. Triturate rapidly until a creamy white emulsion forms.
4. Add remaining ingredients and make up the volume.

2. Wet Gum Method (English Method)

- Also used for **O/W emulsions**.

Steps:

1. First prepare mucilage of gum with water.
2. Add oil slowly in small portions with continuous trituration.
3. Continue until primary emulsion is formed.

4. Add remaining ingredients and adjust volume.

3. Bottle Method

- Suitable for **volatile or low-viscosity oils**.

Steps:

1. Place oil and gum in a dry bottle.
2. Shake vigorously.
3. Add water in portions with continuous shaking.
4. Complete the emulsion and add remaining ingredients.

4. In-Situ Soap Method

- Emulsifier is formed during preparation.

Example:

- Fatty acid + alkali → soap (emulsifying agent)
- Sodium soap → O/W emulsion
- Calcium soap → W/O emulsion

5. Mechanical Method

- Uses homogenizers or mixers.
- Produces fine and stable emulsions.
- Common in industrial manufacturing.

Stability Problems of Emulsions

Emulsions are physically unstable systems and may show the following problems:

1. Creaming

- Upward or downward movement of droplets due to density difference.
- Does not break emulsion but causes non-uniformity.

2. Cracking (Breaking)

- Complete separation of oil and water layers.
- Irreversible instability.

3. Coalescence

- Small droplets merge to form larger droplets.

4. Phase Inversion

- O/W emulsion changes to W/O or vice versa due to excess phase or temperature changes.

5. Flocculation

- Droplets aggregate without merging.

Methods to Overcome Stability Problems

1. Proper Selection of Emulsifying Agent

- Choose emulsifier with suitable **HLB value**.
- Use correct concentration.

2. Reduction of Droplet Size

- Homogenization reduces droplet size and improves stability.

3. Increase Viscosity of Continuous Phase

- Use thickening agents like CMC, acacia, xanthan gum to reduce creaming.

4. Temperature Control

- Avoid extreme temperature changes during storage.

5. Use of Antioxidants and Preservatives

- Prevent chemical degradation and microbial growth.

6. Controlled Phase Volume

- Avoid excess internal phase to prevent phase inversion.

7. Proper Packaging and Labeling

- Use airtight containers.
- Label with **“Shake well before use.”**

UNIT – III: PRACTICE SET

A. Short Answer Questions

1. Define monophasic liquid dosage forms.
2. What are gargles?
3. Define mouthwashes.
4. What is a syrup?
5. Define suspension.
6. What is flocculation?
7. Define emulsion.
8. What are emulsifying agents?
9. What is creaming in emulsions?
10. What is deflocculated suspension?

B. Long Answer Questions

1. Explain preparation of gargles and mouthwashes.
2. Describe throat paints and ear drops.
3. Explain syrups and elixirs with examples.
4. Define suspensions and explain their advantages and disadvantages.
5. Describe classification of suspensions.
6. Explain flocculated and deflocculated suspensions.
7. Describe preparation of suspensions.
8. Explain definition and classification of emulsions.
9. Discuss tests for identification of type of emulsion.

C. Very Long Answer Questions

1. Describe stability problems of suspensions and methods to overcome them.
2. Explain methods of preparation of emulsions and their stability problems.
3. Write a detailed note on monophasic liquid dosage forms including preparation and uses.

UNIT - IV

SUPPOSITORIES

Suppositories are solid or semi-solid dosage forms intended for insertion into body cavities such as the rectum, vagina, or urethra**,** where they melt, soften, or dissolve at body temperature to produce local or systemic therapeutic effects**.**

They are formulated using suitable suppository bases that release the drug after administration.

Types of Suppositories

Suppositories are classified based on the site of administration**:**

1. Rectal Suppositories

- Inserted into the **rectum**.
- Used for **local effects** such as relief from constipation, hemorrhoids, and rectal inflammation.
- Also used for **systemic effects** when oral administration is not possible.
- Average weight: **1–2 g (adults)** and **~1 g (children)**.
- Shape: **Torpedo-shaped** for easy insertion.

Examples:

- Glycerin suppositories (laxative)
- Paracetamol suppositories (analgesic)

2. Vaginal Suppositories (Pessaries)

- Inserted into the **vagina**.
- Mainly intended for **local action**.
- Used in treatment of **infections, inflammation, and contraception**.
- Weight: **3–5 g**
- Shape: **Ovoid or cone-shaped**

Examples:

- Clotrimazole pessaries
- Metronidazole pessaries

3. Urethral Suppositories (Bougies)

- Inserted into the **urethra**.

- Rarely used.
- Intended for **local anesthetic or antibacterial action**.
- Shape: **Thin, rod-like**
- Weight:
    - Male: ~4 g
    - Female: ~2 g

Examples:

- Local anesthetic bougies

Advantages of Suppositories

1. **Suitable for Patients Unable to Take Oral Medication**
    - Useful for **unconscious, vomiting, pediatric, and geriatric patients**.
2. **Avoids Gastrointestinal Irritation**
    - Drugs that cause gastric irritation orally can be administered rectally.
3. **Bypasses First-Pass Metabolism**
    - Partial avoidance of hepatic first-pass effect improves **bioavailability**.
4. **Local and Systemic Action**
    - Can provide **localized treatment** or **systemic absorption** depending on formulation.
5. **Rapid Onset of Action**
    - Rectal mucosa allows **quick absorption** for some drugs.
6. **Useful in Emergency Conditions**
    - Effective when oral route is not feasible.

Disadvantages of Suppositories

1. **Patient Discomfort and Poor Acceptance**
    - Some patients feel **embarrassment or discomfort**, reducing compliance.
2. **Variable Drug Absorption**
    - Absorption can vary due to **rectal contents, blood flow, and placement depth**.
3. **Storage Problems**
    - Many suppositories **melt at warm temperatures** and require cool storage.
4. **Risk of Expulsion**
    - Suppositories may be expelled before complete drug release.
5. **Limited Drug Dose**
    - Not suitable for drugs requiring **large doses**.
6. **Local Irritation**
    - May cause irritation or inflammation of rectal or vaginal mucosa.

Suppositories are an important alternative dosage form in pharmaceutical practice, especially when oral administration is unsuitable. Their ability to provide both local and systemic effects**,** combined with avoidance of gastric irritation and partial bypass of first-pass metabolism, makes them valuable in clinical therapy. However, factors such as patient acceptability, absorption variability, and storage requirements must be carefully considered during formulation and use.

Types of Suppository Bases

Suppository bases are inactive substances that carry the drug and release it after insertion. Selection of a suitable base is essential for proper drug release and stability.

A. Fatty (Oleaginous) Bases

These bases **melt at body temperature** and release the drug.

1. Cocoa Butter (Theobroma Oil)

- Most commonly used base.
- Melting point close to body temperature (~34–36°C).
- Non-toxic and bland.

Advantages:

- Soothing effect
- Good patient acceptance

Disadvantages:

- Polymorphism (changes in melting point)
- Softens easily at high temperature
- Poor water absorption

B. Water-Soluble and Water-Miscible Bases

These bases **dissolve in body fluids** instead of melting.

1. Glycerinated Gelatin

- Contains gelatin, glycerin, and water.
- Mainly used for **vaginal suppositories**.

Advantages:

- Prolonged action
- Does not melt at room temperature

Disadvantages:

- Hygroscopic (absorbs moisture)
- May cause irritation
- Requires preservatives

2. Polyethylene Glycol (PEG) Bases

- Synthetic, available in various molecular weights.
- Melting depends on molecular weight.

Advantages:

- Chemically stable
- No need for refrigeration
- Suitable for tropical climates

Disadvantages:

- May cause irritation
- Slow drug release

2. Methods of Preparation of Suppositories

A. Hand Molding Method

- Oldest method.
- Base is softened and mixed with drug.
- Molded by hand into suppository shape.

Limitations:

- Non-uniform weight
- Not suitable for large-scale production

B. Fusion (Molding) Method

- Most widely used method.

Steps:

1. Base is melted on a water bath.
2. Drug is dissolved or dispersed in molten base.
3. The mixture is poured into lubricated molds.
4. Allowed to cool and solidify.
5. Suppositories are removed and packed.

Advantages:

- Uniform shape and weight
- Suitable for most bases

C. Compression Method

- Used when drug is sensitive to heat.

Steps:

- Drug and base are blended.
- Compressed into suppositories using special machines.

Advantages:

- No heat involved
- Suitable for thermolabile drugs

DISPLACEMENT VALUE

Displacement value (DV) is defined as the number of parts by weight of drug that displace one part by weight of the suppository base**.**

It helps in calculating the exact quantity of base required when a drug is incorporated.

Importance of Displacement Value

- Ensures uniform weight and dose**.**
- Prevents over- or under-filling of molds.

Calculation of Displacement Value

Formula:

$$\text{Weight of base required} = \text{Weight of blank suppository} - \frac{\text{Weight of drug}}{\text{Displacement value}}$$

EVALUATION OF SUPPOSITORIES

Evaluation ensures quality, safety, and therapeutic efficacy.

1. Appearance and Shape

- Should be smooth, uniform, and free from cracks or air bubbles.

2. Weight Variation Test

- Weigh individual suppositories.
- Weight variation should be within pharmacopeial limits.

3. Melting Point / Softening Time

- Determines how quickly suppository melts or softens at body temperature.

4. Disintegration Test

- Time taken to disintegrate or dissolve in simulated body fluids.

5. Drug Content Uniformity

- Each suppository should contain uniform drug quantity.

6. Breaking Strength (Hardness Test)

- Measures mechanical strength to withstand handling.

7. Liquefaction Time

- Time taken for suppository to liquefy at 37°C under specified conditions.

8. Stability Studies

- Evaluates effect of temperature, humidity, and storage conditions.

Suppositories are valuable dosage forms offering an alternative route of drug administration. Proper selection of base, accurate calculation of displacement value, suitable preparation method, and thorough evaluation are essential to ensure **quality, stability, and therapeutic effectiveness**.

PHARMACEUTICAL INCOMPATIBILITIES

Pharmaceutical incompatibility refers to an undesirable interaction that occurs when two or more drugs, excipients, or pharmaceutical ingredients are combined together**,** resulting in physical, chemical, or therapeutic changes**.** These changes may reduce the efficacy**,** stability**,** or safety of the medication and, in some cases, may make the preparation harmful or unacceptable for patient use.

Incompatibilities are commonly encountered during dispensing, compounding, or prescription processing, and therefore require careful attention by pharmacists.

Classification of Pharmaceutical Incompatibilities

Pharmaceutical incompatibilities are broadly classified into:

1. Physical Incompatibilities
2. Chemical Incompatibilities
3. Therapeutic Incompatibilities

1. Physical Incompatibilities

Physical incompatibility occurs when no chemical reaction takes place**,** but the mixture undergoes physical changes such as precipitation, immiscibility, liquefaction, or crystallization, making the product unacceptable in appearance or use**.**

Causes of Physical Incompatibility

- Insolubility of one ingredient in the solvent
- Mixing of immiscible liquids
- Changes in temperature
- Inadequate solubilization

Types and Examples

a. Insolubility

- Occurs when a substance does not dissolve in the given solvent.
- **Example:**

- Chalk powder in water forms a cloudy mixture.

b. Immiscibility

- Happens when two liquids do not mix uniformly.
- **Example:**
  - Castor oil and water form two separate layers.

c. Precipitation

- Formation of solid particles from solution.
- **Example:**
  - Mixing calcium salts with sulfate solutions produces calcium sulfate precipitate.

d. Liquefaction

- Solid substances become liquid when mixed together.
- **Example:**
  - Camphor + menthol → liquid mixture.

e. Crystallization

- Formation of crystals due to change in solvent or temperature.
- **Example:**
  - Sugar crystallizing from concentrated syrup on cooling.

Prevention

- Use suitable solvents or co-solvents
- Change order of mixing
- Use emulsifying or suspending agents
- Modify formulation technique

2. Chemical Incompatibilities

Chemical incompatibility occurs when chemical reactions take place between ingredients, leading to decomposition, inactivation, or formation of toxic products**.**

Types and Examples

a. Oxidation

- Drug reacts with oxygen.
- **Example:**
    - Adrenaline oxidizes and turns brown on exposure to air.

b. Reduction

- Loss of oxygen or gain of hydrogen.
- **Example:**
    - Potassium permanganate reacts with reducing agents.

c. Hydrolysis

- Reaction of drug with water.
- **Example:**
    - Aspirin hydrolyzes to salicylic acid and acetic acid in moisture.

d. Double Decomposition

- Exchange of ions between compounds.
- **Example:**
    - Silver nitrate + sodium chloride → silver chloride precipitate.

e. Acid-Base Reaction

- Occurs when acidic and basic substances are mixed.
- **Example:**
    - Sodium bicarbonate with citric acid releases carbon dioxide.

Prevention

- Adjust pH
- Use antioxidants and stabilizers
- Protect from light and moisture
- Prepare freshly when required

3. Therapeutic Incompatibilities

Therapeutic incompatibility occurs when two or more drugs interact pharmacologically, resulting in reduced therapeutic effect or increased toxicity**,** even though no physical or chemical change is visible.

Types and Examples

a. Antagonism

- One drug reduces or blocks the effect of another.
- **Example:**
    - Penicillin with tetracycline reduces antibacterial effectiveness.

b. Synergism (Over-potentiation)

- Combined drugs produce excessive effect.
- **Example:**
    - Alcohol with sedatives increases CNS depression.

c. Altered Drug Absorption

- One drug affects absorption of another.
- **Example:**
    - Antacids reduce absorption of tetracycline.

d. Dose Incompatibility

- Prescribed dose is unsafe or inappropriate.
- **Example:**
    - Excessive dose of digoxin leading to toxicity.

Prevention

- Proper review of prescription
- Knowledge of drug interactions
- Dose adjustment
- Consultation with prescriber when needed

Pharmaceutical incompatibilities are important considerations in pharmacy practice, as they can compromise drug safety, efficacy, and patient compliance**.** Understanding the types, causes, and prevention methods of physical, chemical, and therapeutic incompatibilities enables pharmacists to ensure safe dispensing and effective patient care**.**

UNIT – IV: PRACTICE SET

A. Short Answer Questions

1. Define suppositories.
2. What are rectal suppositories?
3. Define displacement value.
4. Name two suppository bases.
5. What is fusion method?
6. Define pharmaceutical incompatibility.
7. What is physical incompatibility?
8. What is chemical incompatibility?
9. Define therapeutic incompatibility.
10. Give one example of oxidation reaction.

B. Long Answer Questions

1. Explain types of suppositories with examples.
2. Describe advantages and disadvantages of suppositories.
3. Discuss types of suppository bases.
4. Explain methods of preparation of suppositories.
5. Define displacement value and explain its importance.
6. Explain evaluation tests for suppositories.
7. Describe physical incompatibility with examples.
8. Explain chemical incompatibility with examples.
9. Discuss therapeutic incompatibility with suitable examples.

C. Very Long Answer Questions

1. Describe suppositories in detail including bases, preparation methods, evaluation, and displacement value calculations.
2. Explain pharmaceutical incompatibilities, their classification, causes, and prevention methods.
3. Discuss different types of incompatibilities encountered in dispensing practice with suitable examples.

UNIT - V

SEMISOLID DOSAGE FORMS

Semisolid dosage forms are pharmaceutical preparations having a consistency between solid and liquid**,** intended mainly for external application to the skin or mucous membranes. These formulations are designed to deliver drugs for local action at the site of application or, in some cases, for systemic absorption through the skin**.** They provide prolonged contact with the skin, thereby enhancing therapeutic effectiveness.

Classification of Semisolid Dosage Forms

Semisolid dosage forms are classified based on their composition and pharmaceutical use:

1. Ointments

- Greasy, semisolid preparations intended for external application.
- Bases may be oleaginous, absorption, water-removable, or water-soluble.
- Used for emollient, protective, or medicated purposes**.**

2. Creams

- Semisolid emulsions (O/W or W/O).
- Less greasy than ointments and more cosmetically acceptable.
- Suitable for inflamed and moist skin conditions**.**

3. Gels

- Semisolid systems consisting of solid particles dispersed in a liquid**.**
- Non-greasy and easily washable.
- Provide rapid drug release**.**

4. Pastes

- Thick semisolid preparations containing a high proportion of finely powdered solids.
- Provide protective and soothing action**.**
- Less penetrating than ointments.

5. Poultices (Cataplasms)

- Soft, moist masses applied warm to the skin.
- Used to relieve pain or inflammation.
- Rarely used in modern therapy.

MECHANISM OF DERMAL PENETRATION OF DRUGS

Dermal penetration refers to the movement of drug molecules from the surface of the skin into the deeper layers or systemic circulation**.**

Routes of Drug Penetration

1. **Transepidermal Route**
    - Most common pathway.
    - Drug passes through the stratum corneum**.**
    - Includes:
        - Intercellular pathway **(between cells)**
        - Transcellular pathway **(through cells)**
2. **Transappendageal Route**
    - Drug enters through hair follicles, sweat glands, and sebaceous glands**.**
    - Contributes minimally but useful for certain drugs.

Steps Involved in Dermal Penetration

1. Drug release from the semisolid base
2. Partitioning into the stratum corneum
3. Diffusion through epidermis and dermis
4. Absorption into systemic circulation (if intended)

FACTORS INFLUENCING DERMAL PENETRATION OF DRUGS

A. Drug-Related Factors

1. **Molecular Size**
    - Smaller molecules penetrate the skin more easily.
2. **Lipid Solubility**
    - Drugs with moderate lipid solubility show better penetration through the stratum corneum.
3. **Drug Concentration**
    - Higher concentration increases the penetration rate.
4. **Ionization**
    - Unionized drugs penetrate the skin more readily than ionized forms.

B. Formulation-Related Factors

1. **Type of Base**

- Ointment bases enhance penetration more than creams or gels.

2. **Presence of Penetration Enhancers**
   - Substances like DMSO, alcohol, or surfactants increase skin permeability.
3. **Viscosity of Preparation**
   - Lower viscosity allows better drug diffusion.
4. **pH of Formulation**
   - Influences drug ionization and skin compatibility.

C. Skin-Related Factors

1. **Condition of Skin**
   - Damaged or diseased skin shows increased penetration.
2. **Thickness of Skin**
   - Thinner skin areas absorb drugs faster.
3. **Hydration of Skin**
   - Hydrated skin allows greater penetration.
4. **Age**
   - Infants and elderly may show altered absorption.

D. Environmental Factors

1. **Temperature**
   - Increased temperature enhances drug absorption.
2. **Duration of Contact**
   - Longer contact time increases penetration.
3. **Occlusion**
   - Covering the application site enhances hydration and absorption.

Semisolid dosage forms play a vital role in topical drug delivery by providing sustained contact with the skin and improved patient compliance. Understanding their **classification, mechanisms of drug penetration, and influencing factors** is essential for designing effective dermatological formulations and ensuring optimal therapeutic outcomes.

OINTMENTS

Ointments are semisolid preparations intended for external application on the skin or mucous membranes. The method of preparation depends on the nature of the drug**,** type of ointment base, and intended therapeutic use**.** Proper preparation ensures uniform drug distribution**,** stability, and effective therapeutic action**.**

Methods of Preparation of Ointments

Ointments are generally prepared by the following two main methods:

1. **Incorporation Method**
2. **Fusion Method**

1. Incorporation Method

Definition

In the incorporation method, the drug is physically mixed with the ointment base without applying heat. This method is commonly used when the drug is stable at room temperature and present in solid or liquid form**.**

Procedure

- Finely powder the solid drug to avoid grittiness.
- Take a small quantity of the ointment base on an ointment slab.
- Incorporate the drug gradually using spatulation **or** trituration**.**
- Add the remaining base in portions until a uniform ointment is obtained.
- Transfer the prepared ointment into a suitable container.

Incorporation of Liquids

- If the liquid drug is miscible with the base, it is mixed directly.
- If immiscible, an absorption base or suitable emulsifying agent is used.

Advantages

- Simple and economical method
- Suitable for heat-sensitive drugs
- Minimal risk of drug degradation

Limitations

- Not suitable for waxy or hard bases
- Uniform mixing is difficult for large quantities

2. Fusion Method

Definition

In the fusion method, the ointment base ingredients are **melted together**, and the drug is incorporated into the molten mass. This method is used when the base contains **solid or waxy components**.

Procedure

1. Ingredients of the base are melted in descending order of their melting points.
2. The molten mixture is stirred gently to ensure uniformity.
3. The drug, if heat-stable, is dissolved or dispersed in the molten base.
4. The mixture is cooled slowly with continuous stirring.
5. Perfumes or volatile substances are added near the end of cooling.
6. The final ointment is packed into suitable containers.

Advantages

- Produces uniform and smooth ointments
- Suitable for large-scale preparation
- Ideal for oleaginous and absorption bases

Limitations

- Not suitable for heat-sensitive drugs
- Risk of air entrapment if not stirred properly

Special Considerations During Ointment Preparation

- **Particle Size:** Solid drugs must be finely powdered to avoid irritation.
- **Uniformity:** Proper mixing ensures even drug distribution.
- **Temperature Control:** Excessive heat may degrade drugs or bases.
- **Order of Mixing:** Ingredients should be added systematically.
- **Packaging:** Ointments should be stored in airtight containers to prevent contamination.

The preparation of ointments requires careful selection of method based on the nature of the drug and base**.** The incorporation method is preferred for heat-sensitive substances**,** while the fusion method is suitable for waxy and solid bases**.** Proper preparation ensures patient safety, stability, and therapeutic effectiveness**,** making ointments an important dosage form in pharmaceutical practice.

PASTES

Pastes are thick semisolid pharmaceutical preparations intended for external application on the skin. They contain a high proportion of finely powdered insoluble solids (usually 25–50%) dispersed uniformly in a suitable base. Because of their stiff consistency, pastes remain in place after application and provide a protective as well as therapeutic effect on the skin.

Characteristics of Pastes

- High solid content
- Stiff and less greasy consistency
- Less penetrating than ointments
- Provide prolonged contact with the skin
- Form a protective barrier

Types of Pastes

1. Fatty Pastes

- Prepared using **oleaginous bases** such as soft paraffin.
- Highly occlusive and protective.

Example:

- Zinc oxide paste

2. Aqueous Pastes

- Prepared using **water-soluble or water-miscible bases**.
- Easily washable and less greasy.

Example:

- Starch paste

Advantages of Pastes

1. **Protective Action**
    - Form a thick protective layer on the skin.
2. **Reduced Skin Irritation**
    - Absorb secretions and reduce moisture.
3. **Localized Effect**
    - Minimal systemic absorption due to limited penetration.
4. **Prolonged Contact**

- Remain at the site of application for longer duration.

5. **Suitable for Inflamed Skin**
    - Preferred in weeping or oozing skin conditions.

Disadvantages of Pastes

1. **Poor Cosmetic Appearance**
    - Thick and difficult to spread.
2. **Limited Drug Penetration**
    - Not suitable when deep penetration is required.
3. **Difficult Removal**
    - Fatty pastes are not easily washable.
4. **Unsuitable for Hairy Areas**
    - Adhere strongly and are difficult to remove.

Method of Preparation of Pastes

Incorporation Method

- Finely powder the solid ingredients.
- Mix the powders uniformly.
- Gradually incorporate the base using spatulation.
- Mix until a smooth, homogeneous paste is obtained.

Note: Fusion method is generally not used because high solid content may lead to uneven distribution.

Uses of Pastes

- Protective applications
- Treatment of diaper rash
- Management of eczema and dermatitis
- Absorption of skin exudates

Examples of Official Pastes

- Zinc oxide paste
- Lassar's paste (zinc oxide + salicylic acid)

Pastes are valuable semisolid dosage forms designed mainly for protective and localized therapy**.** Their high solid content and stiff consistency make them particularly suitable for inflamed and

oozing skin conditions**,** although their limited penetration and poor cosmetic elegance restrict their use in certain cases.

CREAMS

Creams are semisolid pharmaceutical preparations intended for external application to the skin or mucous membranes. They are emulsion-based systems consisting of an oil phase and an aqueous phase**,** stabilized by suitable emulsifying agents. Creams are softer, less greasy, and more cosmetically acceptable than ointments, making them widely used in dermatological therapy.

Classification of Creams

Creams are classified based on the **type of emulsion** they form:

1. Oil-in-Water (O/W) Creams

- Oil droplets are dispersed in a continuous aqueous phase.
- Non-greasy and easily washable.
- Suitable for **weeping and moist skin conditions**.

Examples:

- Vanishing cream
- Hydrocortisone cream

2. Water-in-Oil (W/O) Creams

- Water droplets are dispersed in a continuous oil phase.
- Greasy and occlusive.
- Suitable for **dry and scaly skin conditions**.

Examples:

- Cold cream
- Emollient creams

Advantages of Creams

1. **Good Patient Acceptability**
    - Pleasant appearance and feel.
2. **Easy Application and Spreadability**
    - Smooth texture allows uniform application.

3. **Washable (O/W creams)**
    - Easily removed with water.
4. **Suitable for Inflamed Skin**
    - Less occlusive than ointments, reducing irritation.
5. **Flexible Use**
    - Can provide both local and mild systemic effects.

Disadvantages of Creams

1. **Less Occlusive Than Ointments**
    - Not suitable when deep penetration is required.
2. **Microbial Growth Risk**
    - Aqueous phase supports microbial growth, requiring preservatives.
3. **Lower Stability**
    - Risk of emulsion breakdown on storage.
4. **Shorter Shelf Life**
    - Compared to ointments.

Method of Preparation of Creams

Emulsification Method

Steps:

1. Heat the oil phase and aqueous phase separately to the same temperature.
2. Add the aqueous phase to the oil phase (or vice versa depending on type).
3. Stir continuously until emulsification occurs.
4. Cool the mixture with gentle stirring.
5. Add heat-sensitive ingredients during cooling.
6. Transfer into suitable containers.

Uses of Creams

- Treatment of fungal and bacterial infections
- Anti-inflammatory and antipruritic therapy
- Cosmetic applications
- Moisturizing and emollient action

Examples of Official Creams

- Zinc oxide cream

- Betamethasone cream
- Clotrimazole cream

Creams are versatile semisolid dosage forms offering a balance between effectiveness and cosmetic acceptability**.** Their emulsion nature allows easy application, patient comfort, and wide therapeutic use, especially in dermatological conditions requiring mild to moderate occlusion**.**

GELS

Gels are semisolid pharmaceutical dosage forms in which a liquid phase is immobilized within a three-dimensional network of a gelling agent. This structure provides a jelly-like consistency. Gels are mainly intended for topical application but may also be formulated for ophthalmic, nasal, rectal, or oral use. They are valued for their non-greasy nature, ease of application, and rapid drug release**.**

Classification of Gels

Gels can be classified based on the nature of the dispersion medium and type of gelling system**:**

1. Single-Phase Gels

- Drug and gelling agent are dissolved in the liquid phase.
- Transparent and uniform.
- Prepared using polymers like carbomers or cellulose derivatives**.**

Examples:

- Carbopol gel
- Methyl cellulose gel

2. Two-Phase Gels (Magmas)

- Solid particles dispersed in a liquid medium.
- Appear cloudy or opaque.
- Require shaking before use.

Examples:

- Aluminum hydroxide gel
- Bentonite magma

3. Hydrogels

- Water is the dispersion medium.
- Commonly used for dermatological and wound care**.**

Examples:

- Aloe vera gel
- Lidocaine hydrogel

4. Organogels

- Non-aqueous liquid (oil) is the dispersion medium.
- Used for lipophilic drugs.

Examples:

- Lecithin organogel

Advantages of Gels

1. **Non-Greasy and Easily Washable**
    - Provide good cosmetic acceptability.
2. **Rapid Drug Release**
    - High water content allows quick diffusion of the drug.
3. **Cooling and Soothing Effect**
    - Beneficial for inflamed or burned skin.
4. **Ease of Application**
    - Spread smoothly without excessive rubbing.
5. **Good Patient Compliance**
    - Preferred over oily preparations.

Disadvantages of Gels

1. **Drying Effect**
    - High alcohol or water content may cause skin dryness.
2. **Limited Drug Compatibility**
    - Not suitable for highly lipophilic drugs without modification.
3. **Microbial Contamination**
    - Aqueous gels require preservatives.
4. **Lower Occlusiveness**
    - Less effective for very dry skin conditions.

Method of Preparation of Gels

General Procedure

1. Disperse the gelling agent in water with continuous stirring.
2. Allow sufficient time for hydration and swelling.
3. Add the drug dissolved in a suitable solvent.
4. Adjust pH if required to achieve gel formation.
5. Add preservatives, humectants, or penetration enhancers.
6. Remove entrapped air and pack in suitable containers.

Uses of Gels

- Anti-inflammatory and analgesic therapy
- Antifungal and antibacterial treatments
- Ophthalmic and nasal drug delivery
- Cosmetic and dermatological applications

Examples of Gels

- Diclofenac gel
- Metronidazole gel
- Benzoyl peroxide gel

Gels are important semisolid dosage forms that offer rapid drug release, excellent cosmetic properties, and patient comfort**.** Their versatility and ease of application make them especially suitable for modern topical therapy, though formulation stability and microbial protection must be carefully controlled.

EXCIPIENTS USED IN SEMISOLID DOSAGE FORMS

Excipients are inactive pharmaceutical ingredients added to semisolid dosage forms to provide structure, stability, appearance, and therapeutic effectiveness**.** In topical preparations such as ointments, creams, gels, and pastes**,** excipients play a crucial role in drug release, skin penetration, stability, and patient acceptability**.**

1. Bases

Role

- Form the main body of the semisolid preparation.
- Control drug release and skin hydration.

Types and Examples

- **Oleaginous bases:** White soft paraffin, yellow soft paraffin
- **Absorption bases:** Wool fat, hydrophilic petrolatum
- **Water-removable bases:** Emulsifying ointment
- **Water-soluble bases:** Polyethylene glycol (PEG)

2. Emulsifying Agents

Role

- Stabilize emulsions in creams.
- Prevent phase separation.

Examples

- Natural: Acacia, gelatin
- Semi-synthetic: Cetostearyl alcohol
- Synthetic: Sodium lauryl sulfate, polysorbates (Tween)

3. Gelling Agents

Role

- Provide gel structure and viscosity.

Examples

- Carbopol (carbomers)
- Hydroxypropyl methylcellulose (HPMC)
- Sodium alginate
- Xanthan gum

4. Humectants

Role

- Retain moisture and prevent drying.
- Improve skin hydration.

Examples

- Glycerin
- Propylene glycol
- Sorbitol

5. Preservatives

Role

- Prevent microbial growth, especially in aqueous formulations.

Examples

- Methyl paraben
- Propyl paraben
- Benzyl alcohol
- Chlorocresol

6. Antioxidants

Role

- Prevent oxidation of drugs and bases.

Examples

- Butylated hydroxyanisole (BHA)
- Butylated hydroxytoluene (BHT)
- Ascorbic acid
- Sodium metabisulfite

7. Penetration Enhancers

Role

- Improve drug permeation through skin.

Examples

- Dimethyl sulfoxide (DMSO)
- Oleic acid
- Urea
- Isopropyl myristate

8. Thickening Agents

Role

- Increase viscosity and stability.

Examples

- Cetyl alcohol
- Stearyl alcohol
- Beeswax

9. Buffers and pH Adjusters

Role

- Maintain optimal pH for stability and skin compatibility.

Examples

- Citric acid
- Sodium citrate
- Phosphate buffer

10. Solvents and Co-solvents

Role

- Dissolve drug and other excipients.

Examples

- Purified water
- Ethanol
- Propylene glycol

11. Perfumes and Coloring Agents

Role

- Improve patient acceptability and product appearance.

Examples

- Lavender oil
- Menthol (also provides cooling effect)

Excipients used in semisolid dosage forms are essential for **ensuring stability, effective drug delivery, patient comfort, and product quality**. Proper selection and combination of excipients help achieve the desired therapeutic outcome while maintaining safety and acceptability of topical formulations.

EVALUATION OF SEMISOLID DOSAGE FORMS

Evaluation of semisolid dosage forms is carried out to ensure that the formulation is safe, stable, effective, and acceptable to the patient**.** Semisolid preparations such as ointments, creams, gels, and pastes must meet quality standards related to physical appearance, drug content, consistency, and performance before being used clinically**.**

1. Physical Appearance and Homogeneity

- The product should be smooth, uniform, and free from grittiness**.**
- There should be no phase separation, air entrapment, or lump formation**.**
- Color, odor, and texture should be consistent throughout the preparation.

2. pH Determination

- pH is measured using a digital pH meter**.**
- The pH should be compatible with skin pH (approximately 5.5–7)**.**
- Incorrect pH may cause skin irritation or drug instability.

3. Viscosity Measurement

- Viscosity determines the thickness and flow properties of semisolid preparations.
- Measured using Brookfield viscometer**.**
- Proper viscosity ensures easy application, retention at site, and uniform drug distribution**.**

4. Spreadability Test

- Measures the ease with which the formulation spreads on the skin**.**
- Determined by placing a fixed amount of sample between two glass slides and measuring spread under applied weight.
- Good spreadability improves patient compliance**.**

5. Extrudability Test

- Evaluates the ease of removal of the formulation from collapsible tubes**.**
- A formulation should be easily extrudable without excessive force.

6. Drug Content Uniformity

- Ensures uniform distribution of drug throughout the formulation.
- A fixed quantity of sample is analyzed chemically.
- Results should fall within pharmacopeial limits.

7. In Vitro Drug Release Study

- Determines the rate and extent of drug release from the formulation.
- Usually performed using diffusion cells**.**
- Helps predict in vivo performance.

8. Skin Irritation Test

- Conducted to ensure safety for topical use**.**
- Evaluates redness, swelling, or allergic reaction after application.
- May be performed on animals or using in vitro skin models.

9. Stability Studies

- Assess changes in physical appearance, pH, viscosity, and drug content over time.
- Conducted under different temperature and humidity conditions**.**
- Ensures adequate shelf life.

10. Microbial Limit Test

- Ensures the formulation is free from harmful microorganisms**.**
- Especially important for aqueous and multi-dose formulations**.**

Evaluation of semisolid dosage forms is a critical step in pharmaceutical formulation and quality control. These tests ensure that the product is physically stable, therapeutically effective, microbiologically safe, and acceptable to patients**,** thereby ensuring reliable clinical performance.

UNIT – V: PRACTICE SET

A. Short Answer Questions

1. Define semisolid dosage forms.
2. What are ointments?
3. Define paste.
4. What are creams?
5. Define gels.
6. What is dermal penetration?
7. Name two penetration enhancers.
8. What is occlusion?
9. Define spreadability.
10. What is viscosity?

B. Long Answer Questions

1. Explain classification of semisolid dosage forms.
2. Describe mechanisms of dermal penetration of drugs.
3. Discuss factors influencing dermal penetration.
4. Explain preparation of ointments.
5. Describe preparation of pastes.
6. Explain preparation of creams.
7. Describe preparation of gels.
8. Explain excipients used in semisolid dosage forms.
9. Discuss evaluation tests of semisolid dosage forms.

C. Very Long Answer Questions

1. Discuss semisolid dosage forms in detail including classification, penetration mechanism, and influencing factors.
2. Explain preparation methods of ointments, pastes, creams, and gels with suitable examples.
3. Describe excipients and evaluation parameters of semisolid dosage forms in detail.

Textbook of Pharmaceutics-I

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